

Communities as Partners in Cancer Clinical Trials:

***A Draft Strategic Plan for
Changing Research, Practice and
Policy***

February 2008

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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.

1 **Introduction**

2
3 Cancer clinical trials help to move basic scientific research from the laboratory into
4 treatments for people with cancer. By evaluating the results of these trials, scientists
5 can find better treatments and ways to prevent, detect, and treat cancer. Although about
6 20 percent of cancer patients are medically eligible for a phase III therapeutic cancer
7 clinical trial,^{1 2} trial participation among adult cancer patients remains at two and a half
8 to three percent.³ This rate is even lower among people of color and the medically
9 underserved,⁴ who tend to have higher cancer mortality rates than the population as a
10 whole.

11
12 **Numerous structural, cultural, and linguistic factors negatively affect**
13 **participation in therapeutic cancer clinical trials.** Many of these factors are clearly
14 related to lack of knowledge and underlying attitudes and beliefs on the part of the
15 public as well as health care providers. According to one national survey, 75% of
16 people with cancer would have been interested in participating in a trial, had they known
17 it was available.⁵ Moreover, clinical trial investigators also report great difficulty in
18 identifying appropriate patients for their trials. A recent AHRQ report on cancer clinical
19 trial recruitment confirmed that there is substantial uncertainty about effective
20 approaches for cancer clinical trials recruitment, especially among minority populations.⁶

21
22 **The low accrual rate in therapeutic cancer clinical trials, especially among racial**
23 **and ethnic minorities, the elderly and other medically underserved groups, has a**
24 **significant effect on both the quality of research and the rate at which new**
25 **scientific discoveries are made.**^{7 8 9} Cooperative group trials often struggle to accrue
26 patients; in phase III studies of ECOG and CALGB, preliminary data has shown that
27 about 15-30% were closed due to poor accruals¹⁰.

28
29 Despite NIH guidelines on inclusion of women and minorities as subjects in clinical
30 research, only 11% of cancer patients enrolled in national publicly funded treatment
31 trials are ethnic/cultural minorities¹¹. As Corbie-Smith and others point out, there are
32 scientific imperatives that underscore the importance of better representation of the
33 racial/ethnic minorities in clinical trials: a) to test specific hypotheses about differences
34 by race and ethnicity (mandating appropriate statistical power to detect those
35 differences); b) to generate hypotheses about possible differences by race and ethnicity
36 (with new targeted therapies, studying populations with different prevalence of relevant
37 genotypic variants are increasingly important); and c) to overcome the inability to
38 generalize findings to the greater population.^{12 13 14 15 16} Moreover, strict eligibility
39 criteria often exclude patients with chronic conditions, which in turn exclude the elderly,
40 members of minority groups, and patients with lower socioeconomic status from
41 participating in trials.^{17 18}

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42 **The low accrual rate in therapeutic cancer clinical trials – also has a profound**
43 **effect on quality of care provided to all patients with cancer.** Access to cancer
44 clinical trials is a key quality measure for delivery of health care services; it is one of the
45 established standards for the delivery of quality comprehensive cancer care.¹⁹ Yet all
46 who are eligible are not offered this opportunity. Other studies have found that
47 minorities with cancer are less likely to be offered participation in a cancer clinical trial,
48 that patients enrolled in cancer clinical trials are significantly more likely to be insured,
49 and that geographic areas with higher socioeconomic levels have higher levels of
50 cancer clinical trial accrual.^{20,2122}

51
52 **The low accrual rate in therapeutic cancer clinical trials is simply a matter of**
53 **social justice.** Principles of social justice demand better representation of all groups in
54 cancer clinical trials to: a) ensure equal access to clinical trials;^{23 24} b) ensure the just
55 distribution of the benefits and burdens of participation in research;²⁵ and/or c) address
56 the impact of cancer health disparities.²⁶

57
58 **Experts continually recommend community-based approaches to enhance**
59 **accrual**, noting that “success [in clinical trials accrual] will require sustained, aggressive
60 action, and new partnerships between policymakers, healthcare professionals,
61 professional societies, and underserved communities.” In its 2005 report, the President’s
62 Cancer Panel emphasized that “both trust . . . and community participation are essential”
63 to the success of clinical research.²⁷ The Clinical Research Roundtable at the Institute
64 of Medicine acknowledged that the state of clinical research today “may hinge on the
65 willingness and ability of the scientific community to actively engage study participants
66 in every stage of research, implanting a community based participatory research
67 model.”²⁸

68
69 **Community-based participatory research (CBPR)** offers the potential for improving
70 research quality and outcomes, and enhancing research recruitment efforts,²⁹ and has
71 been recommended as a way to improve the state of clinical research participation.³⁰
72 The intent in CBPR is to transform research from a relationship where researchers *act*
73 *upon* a community to answer a research question to one where researchers *work side*
74 *by side with* community members to define the questions and methods, implement the
75 research, disseminate the findings and apply them. Community members become part
76 of the research team and researchers become engaged in the activities of the
77 community. CBPR approaches have been utilized in public health research since the
78 1980s and notably in clinical research in HIV/AIDS since the mid-1990s.

79
80 ***Communities as Partners in Cancer Clinical Trials: Changing Research, Practice***
81 ***and Policy*** is a joint initiative of ENACCT (The Education Network to Advance Cancer
82 Clinical Trials) and CCPH (Community-Campus Partnerships for Health), with core
83 funding from the Agency for Healthcare Research and Quality (AHRQ) and the National
84 Cancer Institute (NCI). This three-year national effort is exploring the potential of

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

89
90 In September 2007, seventy representatives from community-based organizations,
91 patient advocacy groups, cancer centers, schools of medicine and public health, the
92 pharmaceutical industry, Federal health agencies and local oncology practices
93 convened in the DC area for the first of three invitational meetings, to lay the
94 groundwork for a strategic plan for strengthening community engagement in Phase III
95 cancer clinical trials.

96
97 At the meeting, participants discussed the issues and challenges facing the U.S. cancer
98 clinical trial enterprise; the opportunities presented by CBPR; and models of community
99 engagement in other areas of therapeutic clinical research. Participants worked in small
100 and large groups to identify institutional and system barriers that inhibit greater
101 community engagement in therapeutic cancer clinical trials and to explore the
102 application of CBPR principles to key areas of the clinical research process. A framing
103 background paper and invited commentaries sent to participants prior to the meeting
104 helped to inform the deliberations.³¹

105
106 Building on the foundation established at the meeting, participants in the **Communities**
107 **as Partners** project were organized into three distinct workgroups: a) National Level
108 Trial Design and Implementation; Local Level Trial Implementation; and National and
109 Local Data Analysis, Interpretation and Dissemination. These workgroups were charged
110 with developing specific recommendations for community engagement in phase III
111 cancer treatment trials.

112
113 A set of guiding principles has informed the workgroups' efforts. These principles
114 helped to ensure that the recommendations reflect:

- 115
- 116 • An appreciation for the commitment of both researchers and patient advocates in
117 the cancer clinical trial system who are currently working to engage communities
118 in clinical trials and a desire to build upon their efforts. We acknowledge that we
119 are not "starting from scratch" and that great work is already going on, but it is
120 undervalued, under-funded and not consistently practiced across the cancer
121 clinical trial system.
 - 122
 - 123 • An understanding that while we are challenging the cancer clinical trial system to
124 change, we must also work *within* the system. While we recognize that the
125 cancer clinical trial system (with a strong focus on NCI-funded cooperative group
126 and industry sponsored studies) is not perfect, we must engage those involved in
127 it as partners in this effort. While there can be merit in envisioning an entirely new

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128 system built with communities as partners from the start, we believe this is
129 neither realistic nor feasible. We are invested in making the current system more
130 accessible to and involving of communities.
131

- 132
- 133 • An understanding that there are numerous access barriers to clinical trials. While
134 we expect that community engagement strategies will reduce barriers and
135 enhance accrual, we recognize that there are many more problems that require
136 fixing, which is beyond the scope of this project.
 - 137 • An understanding that federal research priority setting and funding will impact
138 these recommendations. Although research priorities and funding are often
139 disease-specific, not tied to the population burden of the disease, and driven by
140 political factors, we must remain focused on our charge to improve the process
141 and outcomes of phase III cancer clinical trials.
142
 - 143 • An understanding that while there are genuine problems with our health care
144 system, including 47 million people without health insurance, the focus of our
145 work is on improving the process and outcomes of phase III cancer clinical trials.
146
 - 147 • An acknowledgement that CBPR in therapeutic cancer clinical trials may not
148 always be possible or feasible. Therefore, the recommendations will not focus
149 exclusively on CBPR, but will also include other community engagement
150 strategies.
151
- 152

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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>

Also, please visit the *Communities as Partners* website at:

<http://www.enacct.org/conference/conference.php>

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160 **Overview - Draft Workgroup Recommendations**

161
162 The *Communities as Partners* workgroups envision a coordinated national-local system
163 that includes trained community/patient representatives, involved in each component of
164 the national research system supporting phase III cancer treatment trials.

- 165
166
 - **At the national level**, where trial design and approval take place, the
167 number of trained community/patient representatives serving on
168 cooperative group protocol and disease committees would be increased,
169 their roles/responsibilities clearly defined, and a transparent recruitment
170 and application process established.
 - **At the local level**, where patient enrollment and the study actually take
171 place, community endorsement of the study and community/patient
172 involvement in study implementation would be ensured by linking the
173 local site investigators and research team to a community advisory board
174 and increasing the number of trained community/patient representatives
175 on institutional review boards (IRBs).

176
177
178
179 The following draft recommendations reflect the full spectrum of the Phase III clinical
180 research system, subdivided into three main areas:

- 181
 - A. National Level Trial Design and Implementation
 - 182 B. Local Level Trial Implementation
 - 183 C. National and Local Data Analysis, Interpretation and Dissemination

184
185
186

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187 **NATIONAL DESIGN AND IMPLEMENTATION OF PHASE III TRIALS**

188

Draft recommendations A1 – A10 concern the following components of the national system:

- Establishment of the Study Committee/ Cooperative Group Study Committee
- Identification of research question(s)/ concept paper development
- Design of Trial Protocol
- Submission of Protocol for Review/ Approval/ Funding
- Development of Consent Forms

190

197 **Background**

198
199 ***Establishment of the Study Committee/ Cooperative Group Study Committee – How this works***
200 ***currently:***

201
202 Within cooperative groups, study committees operate within standing disease committees (i.e., breast,
203 colon); modality committees (i.e. surgery, pharmacology); patient oriented committees (i.e., behavioral,
204 cancer control, outcomes) or working groups. Most groups have an appointed membership, with a
205 committee chair. Volunteer physicians, nurses and other researchers meet twice a year and through
206 teleconferences – primarily within disease or modality committees--to design new trials and review trial
207 progress. The group executive committee approves all trials before seeking approval by the NCI.
208 Selected advocates (mostly survivors) may be appointed to serve on certain committees. While all
209 cooperative groups have influential patient advocate members, their role and influence varies on
210 individual committees. Within industry trials, it is rare that community/patient representatives are included
211 in the membership of study committees.

212
213 ***Identification of research question(s); concept development/protocol design; submission of***
214 ***protocol for review/ approval/funding - How this works currently:***

215
216 Within cooperative groups, once the committee's concepts are vetted and approved by the Group, the
217 concept is submitted to NCI for approval, at which point a protocol can be designed. The NCI reviews
218 concepts and protocols for redundancy, scientific merit, and patient safety and ethics considerations.
219 Several newer initiatives (Intergroup, Concept Evaluation Panels, the Clinical Trials Support Unit and the
220 Central IRB) have been designed to reduce time for review. It is unclear if the number or types of clinical
221 trials opened for a particular cancer are proportionate to cancer incidence, mortality, or burden to a
222 particular population. Within industry, once a concept or research question has been identified internally,
223 a clinical team will be assigned to design the draft protocol. This draft protocol will be reviewed by the
224 study team members including clinical operations, statisticians, safety, and data management. Prior to
225 finalizing the protocol, outside experts will review and comment. The protocol is then submitted for
226 finalization by the industry advisory board.

227
228 ***Consent Form Development – How this works currently:***

229
230 *NCI cooperative group trials:* NCI has an “easy to read” template and requires its use for cooperative
231 group studies. To receive approval to begin a study, each cooperative group submits the final protocol to
232 NCI with a consent form; it is simultaneously submitted to the Central IRB. Once approved, local
233 investigators may need to submit the form to their own IRB before enrolling patients. The consent form is
234 included as a part of the final protocol approval process. *Industry* trials generally use a template that

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

237
238 In 1995, the HHS Office of Human Research Protections (OHRP) approved the use of a "short form" as a
239 way to implement the Common Rule's mandate that informed consent information is to be presented "in
240 language understandable to the subject." It clarified the procedures used with subjects who do not speak
241 English, and specific roles for the IRB. In 1998, the FDA issued additional guidance for LEP populations.
242 However, no cooperative group educates its members in use of the short form, nor does the CIRB permit
243 its use.

244
245

246 **Recommendations for NCI and Cooperative Groups¹:**

247

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

252

253

- Modify each standing committee's membership, so that it includes at least
254 10% or two community/patient representatives, whichever is greater; or

255

256

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

260

261 **A2.** Cooperative groups should establish an open, transparent process³² with specific
262 criteria for recruiting community/patient representatives. The opportunity to serve should
263 be widely communicated both to traditional and non-traditional sources of potential
264 representatives, with local cancer experience.³³

265

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

269

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

273

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

276

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

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

279
280 **A7.** NCI's Central Institutional Review Board (CIRB) should only approve applications
281 with consent forms containing evidence of community/patient review and endorsement.
282 In addition, the CIRB should permit and encourage cooperative groups to utilize the
283 OHRP approved "short form," with specifically directions for its use.

284
285 **Recommendations for All Public and Private Study Sponsors:**

286
287 **A8.** All study sponsors should have appropriate community representation at the
288 national level, as outlined above.

289
290 **A9.** All study sponsors should have appropriate community representation in developing
291 informed consent forms, as outlined above.

292
293 **A10.** All study sponsors should establish specific criteria and guidance for use of the
294 "short form," and assist local study teams and IRBs in their approval.

295
296
297 **Rationale for community involvement in trial design at the national level:**

298
299 A number of national reports have called for the inclusion of public representatives in
300 designing clinical research to improve the entire research process;^{34,35,36,37,38} There are
301 several national initiatives that illustrate the feasibility of implementing a group such as
302 a national community advisory board for clinical research³⁹. Currently, federally funded
303 clinical trials in HIV/ AIDS have a number of policies that mandate the inclusion of public
304 representatives in designing clinical research. For example, in order to receive funding
305 announced through NIAID HIV/AIDS Clinical Trials Networks (similar to the cooperative
306 group system), researchers must document meaningful community partnerships; their
307 applications must include the establishment and maintenance of one or more CABs to
308 represent the local population(s) impacted or threatened by HIV/AIDS at the clinical
309 research site(s); and present the research to be conducted to the community. Other
310 policies are listed at the end of this document.^{40 41 42}

311
312 In cancer clinical research, there is an increasingly visible role of advocates within: a)
313 NCI-funded Cancer Cooperative Groups⁴³; b) Specialized Programs of Research
314 Excellence (SPORE) projects and cores;^{44,45} c) U.S. Department of Defense Research
315 Programs;⁴⁶ and d) the California Breast Cancer Research Program. The literature has
316 documented the important role of patient advocates in clinical research study
317 development and implementation, especially in HIV/AIDS, and cancer research.^{47, 48, 49,}
318 ⁵⁰

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

326
327 **Rationale for community involvement in trial implementation at the national level:**

328
329 ***On informed consent:*** Despite extensive national, cooperative group, institutional, and
330 departmental reviews, consent forms from clinical oncology protocols are written at a
331 level that is difficult for most patients to read (written at an 11th or 14th grade level)⁵¹ and
332 are between 20-40 pages in length. The Institute of Medicine estimates that 90 million
333 adults in the United States may have trouble understanding and acting on health
334 information,⁵² and although the average American adult has achieved at least a twelfth
335 grade education, the average reading level for American adults is estimated to be at the
336 eighth or ninth grade.⁵³

337
338 As summarized by ASCO: “The informed consent process has real potential to
339 overwhelm patients. This is especially true because the evolving environment of clinical
340 research seems to place emphasis on the informed consent document as a regulatory
341 or legal protection for the institution and investigator. As a result, the language used in
342 informed consent documents is increasingly legal and scientific in nature. Experts agree
343 that the documents are difficult for potential trial participants to comprehend because of
344 this complex, legalistic language ...Where possible, the consent form should be
345 simplified to optimize comprehensibility and clarity, reduce intimidating language, and
346 place potential benefits and risks...”

347
348 Despite the use of the NCI template in the cooperative group system, nationally
349 developed consent forms still need improvement.

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363

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**

370

371 **Background**

372

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

374

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

377

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

379

380 For cooperative groups, the NCI grants five-year U10 cooperative agreements from the 12 national
381 cooperative groups. This funding supports the cooperative group infrastructure and reimburses
382 approximately 60% of research costs to individual investigators. Remaining costs are offset through
383 agreements with pharmaceutical companies. It is unclear if there is community participation in the NCI
384 cooperative agreement application process. Regarding which trials are ultimately approved for
385 implementation by CTEP, it is unclear if the number or types of clinical trials opened for a particular
386 cancer are proportionate to cancer incidence, mortality, or burden to a particular population.
387 Within industry, study teams are required to assemble annual proposals that include strategy and
388 proposed budgets for further study of investigational drugs. A team will review and determine what
389 studies will be implemented in the following year.

390

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

393

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

397

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

399

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

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410 **Recommendations for NCI and Cooperative Groups:**

411
412 **A11.** As a part of the U10 cooperative agreement, NCI should require that cooperative
413 groups include national communication plans, templates and guidelines for each
414 protocol, which are informed by national community/patient representatives, with a
415 focus on local customization and implementation.

416
417 **A12.** NCI should include trained community/patient representatives in its review of all
418 U10 cooperative agreement applications, renewable every five years.

419
420 **A13.** As a part of the U10 cooperative agreement, NCI should require that all
421 participating investigators within each cooperative group document meaningful
422 connections with local communities, which should advise on the appropriateness of
423 implementation of a trial at the local level. This may be accomplished through **either:** 1)
424 utilization of a local community advisory board (CAB); and/or; 2) meaningful
425 partnerships with community organizations (as detailed in the Local Implementation
426 Section of the document).²

427
428 **A14.** As a part of the U10 cooperative agreement, NCI should require that each
429 cooperative group document how its members demonstrate cultural competency in the
430 research setting. This may be indicated by: 1) yearly clinical research cultural
431 competency programs; 2) the use of patient navigators or outreach workers; or 3) the
432 hiring of local staff that can relate to the participants, have similar backgrounds,
433 understand the participants' experiences, speak their language and are respectful of
434 community structures.

435
436 **A15.** As a part of the U10 cooperative agreement, NCI should require that each
437 cooperative group DSMB **modify its membership to include at least 10% trained**
438 **community/patient representatives or two people, whichever is greater.** All
439 cooperative group DSMBs should prepare an annual progress/safety report for each
440 trial, which should be written lay language and should include information above and
441 beyond serious adverse events. The local investigator should distribute the report to all
442 study participants and a summary of the report should be simultaneously posted on the
443 cooperative group's website.

444
445
446 **Recommendations for All Public and Private Study Sponsors:**

447
448 **A16.** All groups responsible for developing and approving new trials are required, as a
449 condition of funding, to have appropriate community representation in developing
450 communication plans, as outlined above.

² In either case, there must be specific guidelines about membership, responsibilities, and how the individual represents, engages with and reports to the community.

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451
452 **A17.** All groups responsible for developing and approving new trials are required, as a
453 condition of funding, to have appropriate community representation in approving funding
454 of new clinical trials.

455
456 **A18.** All groups responsible for developing and approving new trials should allocate
457 funds for local community education on clinical trials, which are not study specific.

458
459 **A19.** All groups responsible for developing and approving new trials should require
460 proof of ongoing communication between DSMB and investigators, local IRBs, the
461 public, and trial participants.

462
463 **Rationale for community involvement in trial implementation at the national level:**

464
465 **On recruitment:** While individual research teams have little time for recruitment and
466 retention planning, the development of national recruitment strategies, based on target
467 population characteristics at the national level, may increase the likelihood of
468 recruitment success. It is erroneous to assume that all trial participants will come from
469 passive recruitment efforts, such as flagging charts. Key reasons for recruitment
470 problems are: inappropriate match between a trial and a community; inadequate
471 planning at all levels of the trial; overestimation of the yield from a particular patient
472 source; and an inability to alter existing plans rapidly and to implement other recruiting
473 strategies if recruitment is lagging.

474
475 **On approval of funding:** A number of initiatives include public representatives in the
476 funding approval process for clinical research. These include the following:

477
478 ● DOD Congressionally-Directed Medical Research Programs: In order to ensure that
479 research funding decisions reflect the concerns and needs of patients, the clinicians who
480 treat them, and survivors and their families, the U.S. Department of Defense's
481 Congressionally-Directed Medical Research Programs **mandates** inclusion of consumers as
482 full members on all review and advisory panels to make recommendations for funding. Its
483 Breast Cancer Research Program was the first to include consumer reviewers on every
484 review and advisory panel, including those reviewing basic science proposals.

485
486 ● California Breast Cancer Research Program (CBCRP): With the CBCRP, collaboration
487 among scientists, breast cancer organizations and individuals involved in breast cancer
488 issues was mandated by legislation. Each of the CBCRP's peer review committees includes
489 two community advocates who serve as voting members and a nonvoting observer who
490 provides feedback on the process. The CBCRP council, which includes five breast cancer
491 advocates, provides vision, sets research priorities, and determines how funds are invested.

492
493 **On cultural competency:** Many researchers experience difficulties when discussing
494 trial participation, leading to poor trial accrual and questionable quality of informed

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495 consent.⁵⁴ Researchers are further challenged when recruiting and consenting
496 ethnically diverse populations to clinical trials.⁵⁵ Many investigators and their staff lack
497 the skills necessary for conducting culturally sensitive community outreach and
498 education programs about clinical trials.⁵⁶ Recently, federal officials have underscored
499 the need for cultural competency training in the research setting, convening a national
500 research team to apply National Standards on Culturally and Linguistically Appropriate
501 Services (CLAS) to the clinical trials process³.
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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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503 **LOCAL IMPLEMENTATION OF PHASE III TRIALS**

504

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*

505

506 **Background**

507

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

509

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

515

516 ***Establishing the Local Research Team - How this works currently:***

517

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

521

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

523

524 All clinical trials⁴ must be reviewed and approved by an IRB. Federal regulations require that an IRB
525 include at least five people of diverse occupations and backgrounds; at least one member must have
526 primarily scientific interests, and another member must have primarily non-scientific interests. The IRB
527 reviews the protocol to ensure the study is conducted fairly and participants are not likely to be harmed.
528 The IRB also decides how often to review the trial once it has begun. An ad hoc IRB member may be
529 used for specific types of research.

530

531 **Recommendations for All Public and Private Sponsors:**

532

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

⁴ that are federally funded or that evaluate a new drug or medical device subject to FDA regulation

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540
541 **B2.** Entities that sponsor trials should provide funding for the operation of local CABs,
542 including compensation for CAB members. Possible sources of funding include
543 institutional indirect reimbursement; public-private partnerships; and direct grant
544 funding.

545
546 **B3.** National standards should be established for local cancer research CABs. (Draft
547 standards are listed at the end of the document).

548
549 **B4.** Local research teams should include members of the affected community - in a
550 voluntary or staff capacity. Such individuals should have similar backgrounds to
551 potential study participants, understand the participants' experiences, speak their
552 language and be familiar with community structures.

553
554 **B5.** Research is needed to document and demonstrate the value of community
555 members serving on local CCT research teams.

556
557 **Recommendations for OHRP and FDA:**

558
559 **B6.** For all Phase III CCT studies, an investigator application to the local IRB should
560 include evidence of CAB endorsement of the study. In the absence of CAB
561 endorsement, investigators should document local community organization
562 endorsement.

563
564 **B7.** Local IRB composition should be 20% community (non-scientific, unaffiliated)
565 members, or four individuals, whichever is greater. All community IRB members are
566 properly oriented, trained, mentored and compensated by the IRB sponsoring
567 institution.

568
569 **B8.** Community IRB members should be involved in all aspects of the consent form
570 review process. All IRB members should receive training on alternative ways to
571 address the needs of low literacy and LEP populations in the clinical research consent
572 process.

573
574 **B9.** Both agencies should provide guidance on and encourage use of the "short form."
575 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*

581 **Background**

582
583 ***Communicating trial availability - How this works currently:***
584

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

587 ***Recruiting and identifying potential participants - How this works currently:***
588

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

594 ***Screening, consenting and accruing study participants - How this works currently:***
595

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

600
601 ***Enhancing participant retention - How this works currently:***
602

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

605
606 ***Filing and obtaining periodic IRB review - How this works currently:***
607

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

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620 **Recommendations for All Public and Private Sponsors:**

621
622 **B10.** Institutions in which research is being conducted should collaborate with the
623 existing community infrastructure (e.g., primary care clinics, churches, and
624 neighborhood associations), to communicate information about trial availability, beyond
625 any particular trial. The institution should also engage in outreach activities with
626 community groups, particularly those working to reduce health disparities, to educate
627 the broader community about cancer clinical trials in general.

628
629 **B11.** The local research team should collaborate with patient navigators and other
630 paraprofessionals involved in patient care, to encourage communication of trial
631 availability to individuals recently diagnosed with cancer. Navigators are trained about
632 the clinical trial process and how to approach patients who have received a recent
633 cancer diagnosis.

634
635 **B12.** All sponsors should require local investigators to develop a recruitment and
636 retention plan for CAB review. Investigators will provide recruitment and retention plan
637 updates to the local IRB, as part of the IRB annual review.

638
639 **B13.** National study sponsors should require that at the institution where research is
640 conducted, all patients are informed about clinical trial availability at time of initial
641 consultation with the oncologist and the cancer treatment team. Patient
642 advocates/navigators are available -- on-site, or at a minimum, by phone - to speak with
643 candidates considering participation in a clinical trial and help them understand the
644 details of a proposed study.

645
646 **B14.** Study sponsors should require that consent is done by trained staff. A navigator
647 should also be available at the patient's request, to assist in the consent process. In
648 the case of LEP individuals, when consent forms are not available in the individual's
649 language, special emphasis should be placed on use of the phone language line during
650 the consent process.

651
652 **B15.** To optimize retention, the local research team should demonstrate respect,
653 acknowledgement and appreciation of trial participants through a variety of means, such
654 as periodic correspondence on the trial, newsletters, cards, and special events. Trial
655 participants should be given the opportunity to discuss their experiences with those
656 considering participation.

657
658 **B16.** NCI should fund research on promising practices in CCT recruitment and retention
659 efforts.

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662 **Recommendations for OHRP and/or FDA:**

663
664 **B17.** Local IRBs should require that annual study progress reports are “translated” into
665 lay language and sent to all trial participants. Investigator must provide proof of ongoing
666 communication with trial participants.

667
668 **B18.** Local IRBs should review investigator updates on the trial recruitment and
669 retention plan, to ensure targets are being met.

670
671 **B19.** Local IRBs should require researchers to keep participants up-to-date on any new
672 study-related information, including adverse reactions, in written and oral forms.

673
674
675 **Rationale for community involvement in trial implementation at the local level:**

676
677 Community advisory boards (CABs) offer a vital link between local investigators and the
678 communities in which research takes place. CAB members act as advocates for the
679 community and as “translators” between the community and research scientists.
680 Moreover, CABS are a promising vehicle for community endorsement of cancer clinical
681 research studies. Partnerships between CABs and local investigators have operated
682 successfully since the early 1990’s within the HIV/AIDS clinical trials system, as well as
683 prevention-related public health research programs. If a CAB has authentic
684 connections to its community, its members can transform attitudes about research.⁵⁷
685 Indeed, some have posited that the focus of the principles of ethical research outlined in
686 the *Belmont Report*⁵⁸ needs to be expanded to include an explicit respect for
687 communities —perhaps through a CAB or other manner of gaining “community
688 consent”—to supplement the individually-focused informed consent process.^{59, 60, 61}

689
690 While recognizing that local IRBs are typically underfunded and overworked,
691 improvements are needed to make IRBs more responsive to community concerns
692 regarding clinical research. Currently, IRBs are focused primarily on assessing risk to
693 individuals. They are not expected or required to assess the benefits of the research to
694 the broader community (rather than to an individual patient) and most IRBs do not make
695 such assessments.⁶²

696
697 Community education is an important part of reducing barriers to clinical trial access
698 and enhancing awareness of treatment options. The only nationwide study conducted
699 to date on cancer clinical trials awareness confirmed that the majority of the public
700 knows little about cancer clinical trials. Findings showed that about 85% of people with
701 cancer were either unaware or unsure that participation in clinical trials was an option,
702 although about 75% said they would have been willing to enroll had they known it was
703 possible.⁶³ At the moment of diagnosis and treatment decision making, the presentation
704 of a clinical trial as a high quality treatment option can be both alienating and

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705 frightening. **Therefore, the optimal “educable” moment to learn about cancer**
706 **clinical trials may not be at the moment of diagnosis.** By enhancing community
707 literacy about clinical trials, it is possible to change social norms, so that when a
708 community member is diagnosed, his/her loved ones, friends and social networks will
709 encourage him or her to inquire about clinical trials as an option for treatment – either to
710 the trusted primary care provider or to the oncologist.
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712 **DATA ANALYSIS, INTERPRETATION AND DISSEMINATION OF**
713 **PHASE III TRIALS**

714

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**

722
723 **Background**

724
725 **Data analysis and interpretation Dissemination - How this works currently:**

726
727 Upon completion of the study, the data are analyzed and interpreted by the sponsor and study team.
728 Researchers report the findings from statistical analysis, publish in peer-reviewed journals, and present at
729 professional meetings. Negative findings are typically not published. Subsequent to release of the results,
730 the standard of care may change and new agents may be approved by the FDA. There is currently no
731 systematic way to determine if all oncologists apply the new knowledge in their practices

732
733 **Recommendations for Federal agencies and study sponsors:**

734
735 **C1.** NIH, CDC and AHRQ should jointly fund a systematic study of community
736 involvement in data analysis and interpretation. Study components should include a
737 literature review and follow-up with authors of papers that report on community-based
738 research to specifically identify the extent and value of community involvement in data
739 analysis and interpretation and how community members can best be prepared for
740 these roles.

741
742 **C2.** Investigators should provide trained community/patient representatives involved in
743 the study (e.g., those serving on their national cancer cooperative group or local site
744 community advisory board) with the opportunity to participate in the team that analyzes
745 and interprets the data. These individuals should be properly prepared and
746 compensated for these roles.

747
748 **C4.** As part of the U10 agreement, NCI should require national cooperative groups and
749 local investigators to articulate plans (including a timeline and budget) for disseminating
750 their study findings (positive, negative and null results) to study participants, patients,
751 their caregivers and the broader community.

752
753 **C5.** As part of the U10 agreement, NCI should require phase III cancer clinical trials to
754 report on study progress and study results in written lay language to all participants as
755 soon as the study is concluded (or halted), and before publication.

756

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757 **C6.** As part of the U10 agreement, NCI should require that completed phase III cancer
758 clinical trials provide a lay summary of the major findings and their implications for
759 inclusion in online clinical trial registries. Such summaries should be co-authored with
760 trained community/patient representatives involved in the study, and should follow easy-
761 to-understand templates.⁶⁴

762
763 **C7.** All national study sponsors should support pilot studies intended to determine the
764 most effective mechanisms for disseminating phase III cancer clinical trial results to
765 study participants, patients, their caregivers and the broader community.

766
767 **C8.** All national study sponsors should support mechanisms for disseminating phase III
768 cancer clinical trials results to study participants, patients, their caregivers and the
769 broader community (e.g., video and web conferences).

770
771 **Recommendations for Cooperative Groups:**

772
773 **C9.** In their consent forms to participate in Phase III cancer clinical trials, cooperative
774 groups should explicitly indicate that study participants will receive study results prior to
775 publication in a form they can understand and act upon.

776
777 **C10.** Cooperative groups should determine if a given Phase III cancer clinical trial has
778 potential policy implications and if so, disseminate findings to relevant policy groups
779 (e.g., health insurers, Centers for Medicare and Medicaid Services, state and federal
780 legislators).

781
782 **Recommendations for Investigators:**

783
784 **C11.** Investigators should invite and include trained community/patient representatives
785 involved in the study (e.g., those serving on their national cancer cooperative group or
786 local site community advisory board) to participate in the team that writes manuscripts,
787 gives presentations and responds to media requests on the study. These individuals
788 should be properly prepared and compensated for these roles.

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790
791
792 **Recommendations for Publishers (e.g., Journals, Clinical Trial Registries, Popular
793 Media):**

794
795 **C12.** When journals review manuscripts that report on findings from phase III cancer
796 clinical trials, they should include in their review criteria an assessment of
797 community/patient representative involvement in the study.

798

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799 **C13.** When journals review manuscripts that report on findings from phase III cancer
800 clinical trials, they should include trained community/patient representatives as
801 manuscript reviewers. These reviewers could be drawn from already trained
802 community/patient representatives who serve on national cancer cooperative groups,
803 local community advisory boards and IRBs. These individuals should be properly
804 prepared and compensated for these roles.

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

813 **C15.** Clinical trial registries, such as <http://www.clinicalstudyresults.org>, should publish
814 lay summaries of phase III cancer clinical trial findings and their implications.

816 **Recommendations for Cancer-Focused Organizations:**

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

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

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

832 **Rationale for Recommendations in Data Analysis, Interpretation and
833 Dissemination**

834
835 CBPR practitioners point to the value of community member involvement in data
836 analysis and interpretation from a number of standpoints: community members can
837 situate the data within their local social and cultural context; contribute to culturally
838 relevant interpretations; and, understanding what the data shows, are more likely than
839 academic researchers to apply the findings in their communities. As there are no
840 published reports of non-scientists involved in analyzing or interpreting data from Phase
841 III cancer clinical trials, this is an area that is ripe for research and development.

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842
843 Cancer clinical trial researchers routinely disseminate positive study findings through
844 publications in peer-reviewed journals and presentations at conferences that reach
845 research and clinical oncologists. Although these are important mechanisms for
846 reaching professional audiences, there is ample evidence to support that journal articles
847 and conference presentations do not by themselves lead to changes in clinical practice.
848 Furthermore, in many cases, these vehicles for dissemination are not readily accessible
849 or understandable to study participants, patients, their caregivers or the broader
850 community.⁶⁵ A related concern is the bias toward publishing and presenting study
851 findings only when they are positive.

852
853 There are a number of efforts underway that are intended to disseminate clinical
854 research findings to the public. These are a promising start, but are not consistently
855 utilized by phase III cancer clinical trial study sponsors, researchers, study participants,
856 patients, their caregivers or the broader community. As patients and the broader
857 community are informed about the results of phase III cancer clinical trials and their
858 implications for patient care, they may increase their level of health literacy and be
859 empowered to ask questions about the standard of health care they receive and the
860 evidence base that underlies decisions being made about their health care. Further,
861 they may be more supportive of clinical trials and more likely to participate in them.

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Local and National Community Representation Definitions

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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.⁶⁶

For our purposes, we define “community” as “those whose well-being is likely to be affected by the conduct of the research.”⁶⁷ 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 disproportionally 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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Qualifications⁵ for Serving as a Community/patient advocate representative

<u>To serve on a National Cooperative Group, an individual must demonstrate...</u>	<u>To work with Local Investigator(s)/Institutions, such as within a Community Advisory Board, an individual must demonstrate...</u>
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 ⁷ 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	

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913

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

To effectively serve on a National Cooperative Group, an individual must demonstrate the following skills	To effectively work with Local Investigator(s)/Institutions, such as within a Community Advisory Board, an individual must demonstrate the following skills
<ol style="list-style-type: none"> 1. Interest and ability to network with other organizations with an interest in cancer 2. A level of comfort articulating personal opinion assertively and professionally among persons of all types of educational and professional backgrounds 3. Self-confidence to ask questions of physicians and scientists, and to disagree with them when necessary 4. The ability to interact effectively with clinical and laboratory researchers 	

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Competencies/knowledge needed for Community/patient advocate representatives

To serve on a National Cooperative Group, an individual must have knowledge in these areas...	To work with Local Investigator(s)/Institutions, such as within a CAB, an individual must have knowledge in these areas...
<ol style="list-style-type: none"> 1. A basic understanding of the disease being studied, including standard of care 2. A basic understanding of the cancer clinical research process 3. Key aspects of community outreach and accessible communication and education strategies 4. Key aspects of health literacy and discerning readability of written documents 5. The cancer clinical research system in the United States; 6. Belmont Report and ethical requirements for research 7. Informed consent process 	
<ol style="list-style-type: none"> 8. Ability to apply scientific concepts and knowledge to analyze complicated proposals in both written and verbal forms. 9. Basic clinical concepts (screening, treatment, staging, prognosis). 10. Basic science concepts (cellular behavior, genetics) 11. Epidemiological concepts (incidence and prevalence, risk, study design, randomization) 12. Basic statistics (p-value, confidence interval, odds ratio, risk ratio) 13. Ethical principles of research as outlined in the Belmont report 14. How new cancer treatments are developed (from laboratory to phase 3 study to FDA approval) 15. The culture, function and procedures of the peer review process 	

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Community/Patient Representatives Serving on National Cooperative Groups

Responsibilities (for review of both concepts and protocols)	Expectations	Training Resources
<ul style="list-style-type: none"> • Judge the feasibility of trial concept (i.e., Is this something that will be of interest to patients?) • Evaluate the relative priority of the trial with respect to other research questions (i.e., How important will the results be to patients?) • Consider potential patient experience in trial (i.e., How does the trial experience compare to standard care?) • Consider eligibility criteria that can best meet the needs of those disproportionately impacted by the disease • Review the consent form, to ensure comprehensibility and clarity in a number of areas⁶⁸ • consider review of all patient documents, with an understanding of basic concepts in addressing health literacy 	<ul style="list-style-type: none"> • Attend orientation and training • Use formal criteria and standard forms, such as PROJECT INFORM (used in ACRIN). • Invest time reviewing protocols/concepts • Invest time attending meetings • Participate and vote in calls and in-person review meetings. • Adhere to specific term limits 	<ul style="list-style-type: none"> SPORE "PART" Program NBCC's Project LEAD NCI's CARRA training program NCI's Cancer Information Service Partnership Program Genetic Alliance CISN C3 Research Advocate Training Project TRES, UCSD

Draft Local CAB (Community Advisory Board) Standards

CAB Membership	Roles and responsibilities of CAB members	Informational needs re: CAB operations
<ul style="list-style-type: none"> Representatives of local communities disproportionately impacted by cancer morbidity or mortality at the clinical research site survivors and family members who have experience with different types of cancer clinical trial participants religious leaders primary health care providers 	<ul style="list-style-type: none"> Review study concepts and protocols for community relevance Pre-test study materials; particularly for cultural sensitivity Review recruitment and retention plan Evaluate the study's accessibility to underserved populations, including low literacy and LEP (limited English proficiency) individuals, racial and ethnic minorities, and people living with disabilities. Assist investigators in implementing outreach and recruitment efforts 	<ul style="list-style-type: none"> Establishing and funding CABs Building CAB-investigator relationships CAB member training Local and national CAB interface A CAB review checklist, for scoring prospective studies Best practices for CAB involvement in recruitment efforts

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922 **Endnotes**

923

¹ Harnessing Science: Advancing Care by Accelerating the Rate of Cancer Clinical Trial Participation Hearing before the Committee on Government Reform House of Representatives One Hundred Eight Congress Second Session May 13, 2004 Serial No. 108-189 Retrieved 2007 from GPO Access Web site: <http://www.gpoaccess.gov/congress/index.html>; <http://oversight.house.gov>

² National Institutes of Health, National Cancer Institute. (1997). *Report of the National Cancer Institute, Clinical Trials Program Review Group* http://deainfo.nci.nih.gov/advisory/bsa/bsa_program/bsactprgmin.htm
National Cancer Institute. (2002). *Cancer clinical trials: A resource guide for outreach, education, and advocacy* [On-line]. Available: www.cancer.gov/clinicaltrials/resources/outreach-education-advocacy;
National Institutes of Health, National Cancer Institute. (2003). *Digest Page: Boosting Cancer Trial Participation*. Available: <http://cancer.gov/clinicaltrials/digestpage/boosting-trial-participation>

³ Sateren, W. B., et al. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology*, 20, 2109-2117.
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Digest Page: Boosting Cancer Trial Participation. Retrieved 2006 from National Institutes of Health, National Cancer Institute Web site: <http://cancer.gov/clinicaltrials/digestpage/boosting-trial-participation>

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.

⁵ Comis, R. L., et al. (2000). A quantitative survey of public attitudes towards cancer clinical trials. Retrieved 2002 from Coalition of Cancer Cooperative Groups Web site: www.cancertrials-help.org/static_binary/308-9.pdf.

Comis, R. L., et al. (2003). Public attitudes toward participation in cancer clinical trials. *Journal of Clinical Oncology*, 21, 830-835.

⁶ Ford, J.G., et al. (2005). Knowledge and access to information on recruitment of underrepresented populations to cancer clinical trials. *Evidence Report: Technology Assessment (Summary)*, (122) 1-11.

⁷ Ford, J.G., et al. Joffe, S. & Weeks, J.C. (2002). Views of American oncologists about the purposes of clinical trials. *Journal of the National Cancer Institute*. 94(24), 1847-1853.

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⁸ Spilker, B., & Cramer, J. A. (1992). *Patient recruitment in clinical trials*. New York: Raven Press.

⁹ Demmy TL, et al (2004) Managing accrual in cooperative group clinical trials. *J Clin Oncol*. 22(15):2997-3002.

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¹⁰ Dilts, D 2008, private correspondence

¹¹ Source: Baseline Study of Patient Accrual Onto Publicly Sponsored Trials,” Coalition of Cancer Cooperative Groups for the Global Access Project, National Patient Advocate Foundation, April 2006.

¹² Stewart Participation in Surgical Oncology Clinical Trials: Gender-, Race/Ethnicity-, and Age-based Disparities *Annals of Surgical Oncology* 14(12):3328–3334

¹³ Corbie-Smith, G., W.C. Miller, & D.F. Ransohoff. (2004). Interpretations of ‘appropriate’ minority inclusion in clinical research. *American Journal of Medicine.* 116(4), 249-52.

¹⁴ Ford JG, Howerton M. The science of recruiting minority populations to screening trials. *Clin Trials.* 2004;1(4):341-2.

¹⁵ Corbie-Smith, G., W.C. Miller, & D.F. Ransohoff. (2004). Interpretations of ‘appropriate’ minority inclusion in clinical research. *American Journal of Medicine.* 116(4), 249-52.

¹⁶ Ford JG, Howerton M. The science of recruiting minority populations to screening trials. *Clin Trials.* 2004;1(4):341-2.

¹⁷ Ford, J.G., et al.

¹⁸ JK. Keller, et al. Poor access to clinical trials among newly diagnosed adult cancer patients in the community—1999–2004. *Community Oncology.* November 2007

¹⁹ As noted by The American College of Surgeons Commission on Cancer, which sets standards for quality multidisciplinary cancer care delivered primarily in hospital settings. *Cancer Program Standards, 2004: Standard 5.1: Information about the availability of cancer-related clinical trials is provided to patients through a formal mechanism. Standard 5.2: as appropriate to the category, the required percentage of cases is accrued to cancer-related clinical trials on an annual basis. Standard 5.3: provision of clinical trial information and patient accrual to cancer related clinical trials.*

²⁰ Simon, M. S., & Du, W. (2004). Factors associated with breast cancer clinical trials participation and enrollment at a large academic medical center. *Journal of Clinical Oncology, 22, 2046-2052.*

²¹ Sateren, W. B., et al. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology, 20, 2109-2117.*

²² A meta-analysis showed that Americans from ethnic and racial minority groups are as willing to take part in health research studies, when invited to do so, as other groups of Americans. These results contradict the widely held belief that minorities are less willing to enroll in research studies. Those in minority groups were less likely to be asked to participate. Wendler, D., Kington, R., Madans, J., Van Wye, G., Christ-Schmidt, H., Pratt, L.A., Brawley, O.W., Gross, C.P., Emanuel, E. (2006). Are racial and ethnic minorities less willing to participate in health research? *PLoS Med, Feb;3(2):e19.*Epub 2005

²³ Brawley, O. (2004). The study of accrual to clinical trials: Can we learn from studying who enters our studies? *Journal of Clinical Oncology, 22(11), 2039–2040.*

²⁴ Stewart. Participation in Surgical Oncology Clinical Trials: Gender-, Race/Ethnicity-, and Age-based Disparities, *Annals of Surgical Oncology* 14(12):3328–3334

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²⁵ Corbie-Smith G, Miller WC, Ransohoff DF. Interpretations of 'appropriate' minority inclusion in clinical research. *Am J Med.* 2004 Feb 15;116(4):249-52.

²⁶ "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.

²⁷ 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.
<http://deainfo.nci.nih.gov/ADVISORY/pcp/pcp04-05rpt/ReportTrans.pdf>

²⁸ Sung, N.S., Crowley, W.F. Jr, Genel, M., Salber, P., Sandy, L., Sherwood, L.M., Johnson, S.B., Catanese, V., Tilson, H., Getz, K., Larson, E.L., Scheinberg, D., Reece, E.A., Slavkin, H., Dobs, A., Grebb, J., Martinez, R.A., Korn, A., Rimoin, D. (2003). Central challenges facing the national clinical research enterprise. *JAMA.* 2003 Mar 12;289(10):1305-6.

²⁹ Viswanathan M., Ammerman A., Eng, E., Gartlehner, G, Lohr, K.N., Griffith, D., Rhodes, S., Samuel-Hodge, C., Maty, S., Lux, L., Webb, L., Sutton, S.F., Swinson, T., Jackman, A., Whitener, L. (2004). *Community-Based Participatory Research: Assessing the Evidence*. Evidence Report/Technology Assessment No. 99 (Prepared by RTI–University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016). AHRQ Publication 04-E022- 2. Rockville, MD: Agency for Healthcare Research and Quality.

³⁰ 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."
2005 Agency for Healthcare Research and Quality (AHRQ) Evidence Report/ Technology Assessment on cancer clinical trial recruitment³⁰ states, Ford, J.G., et al. (2005). Knowledge and access to information on recruitment of underrepresented populations to cancer clinical trials. *Evidence Report: Technology Assessment (Summary)*, (122) 1-11.
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

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information to the media and the public; and 5) Provide sufficient funds for research and encourage community–researcher partnerships.

National Institute of General Medical Sciences. Report of the first community consultation on the responsible collections and use of samples for genetic research. Retrieved 2008 from National Institute of General Medical Sciences Web site:

http://www.nigms.nih.gov/News/Reports/community_consultation.htm.

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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deainfo.nci.nih.gov/advisory/pcp/pcp04-05rpt/ReportTrans.pdf

³¹ The framing background paper and invited commentaries are available at <http://www.enacct.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 lays 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."

Ford, J.G., et al. (2005). Knowledge and access to information on recruitment of underrepresented populations to cancer clinical trials. *Evidence Report: Technology Assessment (Summary)*, (122) 1-11.

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."

Sung, N.S., Crowley, W.F. Jr, Genel, M., Salber, P., Sandy, L., Sherwood, L.M., Johnson, S.B., Catanese, V., Tilson, H., Getz, K., Larson, E.L., Scheinberg, D., Reece, E.A., Slavkin, H., Dobs, A., Grebb, J., Martinez, R.A., Korn, A., Rimoin, D. (2003). Central challenges facing the national clinical research enterprise. *JAMA*. 2003 Mar 12;289(10):1305-6.

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.

National Institute of General Medical Sciences. Report of the first community consultation on the responsible collections and use of samples for genetic research. Retrieved 2008 from National Institute of General Medical Sciences Web site:

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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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³⁸ In its 2005 report, *Translating Research into Cancer Care: Delivering on the Promise*, the President's Cancer Panel made the following recommendations:

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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 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
- ⁴⁰ The National Institute of Allergy and Infectious Diseases (NIAID) has seven clinical research networks involving community members, with specific guidelines about membership, responsibilities, and how principal investigators must interface with the groups.
The AIDS Clinical Trials Group's Guidelines for Community Advisory Boards. Retrieved March 2007 from the AIDS Clinical Trials Group Web site: <http://aactg.s-3.com/pub/docs/cabguide.htm>
- ⁴¹ Terry Beirn Community Programs for Clinical Research on AIDS has a national community constituency group, made of one member from each CAB. Members represent community issues—especially those of traditionally underserved groups -- on the scientific committees and protocol teams.
Add Your Voice: Opportunities for Community Participation in HIV/AIDS Research. Retrieved March 2007 from NIAID website: http://www.niaid.nih.gov/publications/pdf/HVAD2005_addyourvoiceeng.pdf
- ⁴² Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS clinical trials group (PACTG), the HIV Prevention trials Network (HPTN) and the IVI 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)
- ⁴³ Collyar, D. (2005). How have patient advocates in the United States benefited cancer research? *National Review of Cancer*. 5, 73-78.
- ⁴⁴ Vanchieri C. (1998). Patient advocates help researchers avoid "bumps in the road". *J Natl Cancer Inst*. Aug 19;90(16):1193-5.
- ⁴⁵ Collyar, D. (2005). How have patient advocates in the United States benefited cancer research? *Nat Rev Cancer*. Jan;5(1):73-8
- 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/bcpiip.pdf>)
- ⁴⁷ Perotti, J., Railey, E., Smith, M.L., Pope, C. (2006). Role of advocates in research: the Research Advocate Network (RAN) as a model for advocate participation. *J Natl Compr Canc Netw*. Aug;4(7), 644-6

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- ⁴⁸ Parker, B. (2007). The advocate role in clinical study development and partnering with patient advocates in your local institution. *Cancer Treat Res.* 132, 131-41.
- ⁴⁹ Martinez, R.A. (2004). Role of research subject advocates in the development of data safety and monitoring plans. *J Investig Med. Nov;52(7):464-9*
- ⁵⁰ Michaels, M., & Collyar, D. *Research Advocacy in Traditional Research Settings Questions of Influence and Legitimacy in Patient Advocacy: Patient-Centered Strategies for Improving Healthcare Quality.* Sudbury, MA: Jones and Bartlett Publishers, Inc. 2008
- ⁵¹ Grossman SA, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? *J Clin Oncol* 1994;12:2211–2215.
- ⁵² Institute of Medicine. Health Literacy: A Prescription to End Confusion. In Nielsen-Bohlman L, Panzer A, Kindig DA, eds. Washington, DC: National Academy Pr; 2004.
- ⁵³ Davis, Terry C., Williams, Mark V., Marin, Estela, Parker, Ruth M., Glass, Jonathan Health Literacy and Cancer Communication *CA Cancer J Clin* 2002 52: 134-149
- ⁵⁴ [Brown RF](#), [Butow PN](#), [Boyle F](#), [Tattersall MH](#). Seeking informed consent to cancer clinical trials: evaluating the efficacy of doctor communication skills training. *Psychooncology.* 2007 Jun;16(6):507-16.
- ⁵⁵ Sateren, W. B., et al. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology*, 20, 2109-2117; Klabunde, C.N., et al. (1999) Factors influencing enrollment in clinical trials for cancer treatment. *Southern Medical Journal*, 92, 1189-1193.
- ⁵⁶ Cross Cultural Health Care Program, Needs Assessment of Clinical Trial Staff in ENACCT PEP Sites: Tacoma, WA, Boston MA, and Decatur IL; Seattle; March 2007.
- ⁵⁷ Strauss, R.P. et al.
- ⁵⁸ *The Belmont Report: Ethical Principles and Guidelines for The Protection Of Human Subjects Of Research.* Retrieved 2007 from the Mount Sinai School of Medicine Web site:
<http://www.mssm.edu/irb/pdfs/appendix/03.pdf>.
- ⁵⁹ Gostin, L. (1991). Ethical principles for the conduct of human subject research: population-based research and ethics. *Law Med Health Care.* 19,191–201.
- Weijer, C. (1999). Protecting communities in research: Philosophical and pragmatic challenges. *Camb Q Healthc Ethics.* 8, 501–513.
- ⁶⁰ Israel, B., et al.
- ⁶¹ Federman, D., Hanna, K., Rodriguez, L., eds. (2003). *Responsible Research: A Systems Approach to Protecting Research Participants.* Washington, DC: Institute of Medicine, National Academies Press.
- ⁶² Flicker S, Travers R, Guta A, McDonald S and Meagher A. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health.* Published Online April 10, 2007.

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⁶³ Comis, R. L., et al. (2000). A quantitative survey of public attitudes towards cancer clinical trials [Online]. Coalition of National Cancer Cooperative Groups, Cancer Research Foundation of America, Cancer Leadership Council, and Oncology Nursing Society. Available: www.cancertrials-help.org/static_binary/308-9.pdf
Comis, R. L., et al. (2003). Public attitudes toward participation in cancer clinical trials. *Journal of Clinical Oncology*, 21, 830-835.

⁶⁴ A sample template is as follows:

- What is the problem or issue being studied and why is it important?
- Why did the researchers do this particular study?
- Who was studied?
- How was the study done?
- What did the researchers find?
- What were the limitations of the study?
- What are the practical implications of the study?
- Who should be contacted for more information about the study?

⁶⁵ Fernandez CV, Kodish and Weijer C. Informing Study Participants of Research Results: An Ethical Imperative *IRB: Ethics and Human Research*, Vol. 25, No. 3. (May - Jun., 2003), pp. 12-19.

⁶⁶ Israel, B.A., Checkoway, B., Schultz, A., Zimmerman, M. (1994). Health education and community empowerment: conceptualizing and measuring perceptions of individual, organizational, and community control. *Health Education Quarterly*. 21(2), 149-170.

⁶⁷ *From Building Community Partnerships in Research, Recommendations and Strategies, Report to the President from the Secretary, Health and Human Services, February 1998.*

⁶⁸ These are include but are not limited to the following:

- explanation of the nature and purpose of the research and of equipoise in relation to the particular study
- description of procedures to be used
- Standard of care as it compares to the treatment under study
- potential benefits and risks
- appropriate representation of the entire protocol within the document

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