



**Comments on the Implementation of Human Subjects Protection Training and Education Programs  
September 29, 2008**

*Submitted by:*

**Education Network to Advance Cancer Clinical Trials (ENACCT) &  
Community-Campus Partnerships for Health (CCPH)**

*Submitted to:*

**Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science  
Office for Human Research Protections**

**Background**

The Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH) are pleased to submit comments on the Implementation of Human Subjects Protection Training and Education Programs in response to the DHHS request. ENACCT is the only national organization devoted solely to identifying, implementing and validating innovative community centered approaches to cancer clinical trials education. CCPH is the only national organization devoted solely to promoting health through partnerships between communities and higher educational institutions, using community-based participatory research, service learning, broad-based coalitions and other strategies.

Together we are spearheading a national federally funded initiative, *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy*,<sup>1</sup> which is exploring the potential of employing *community-based participatory research* principles and approaches to improve multi-site, phase III cancer clinical trials. Community-based participatory research (CBPR), as defined by the Federal Interagency Working Group on CBPR<sup>2</sup> and subsequently adopted by the NIH Scientific Interest Group on CBPR,<sup>3</sup> is “scientific inquiry conducted in communities in which community members, persons affected by the condition or issue under study and other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work, including conception, design, conduct, analysis, interpretation, conclusions and communication of results.” Our forthcoming national report<sup>4</sup>, to be released in October 2008, makes a number of recommendations relevant to the issue of training and education of clinical research teams and IRB members, for which OHRP is seeking public comments and guidance. These are summarized below and worded to be broadly applicable to human subjects research.

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<sup>1</sup> *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy* is funded by grant number 1 R13 HS016471 from the Agency for Healthcare Research and Quality, with co-funding from the National Cancer Institute. For more information, visit <http://www.enacct.org/conference/conference.php>

<sup>2</sup> Federal Interagency Working Group on CBPR. <http://www.niehs.nih.gov/translat/IWG/iwghome.htm>

<sup>3</sup> NIH Scientific Interest Group on CBPR. [http://grants.nih.gov/grants/training/esaig/cbpr\\_sig.htm](http://grants.nih.gov/grants/training/esaig/cbpr_sig.htm)

<sup>4</sup> Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH). (2008). *Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy*. Silver Spring, MD and Milwaukee, WI. Available on the ENACCT website at <http://www.enacct.org> and on the CCPH website at <http://www.ccph.info>

## Comments

*A. Need for additional guidance recommending that institutions engaged in human subjects research conducted or supported by the Department of Health and Human Services (HHS) implement training and education programs for certain individuals involved in the conduct, review, or oversight of human subjects research*

We believe that additional guidance is needed to train and educate individuals involved in the conduct, review, and oversight of human subjects research. We believe this training needs to be required and needs to go beyond the content areas currently covered by the OHRP assurance training modules.

For those involved in the conduct of research (e.g., principal investigators, co-investigators, study personnel), we recommend that they be trained in these areas:

1. Engaging communities in research and optimal ways to integrate community members into research activities, including CBPR principles and approaches. This training should enable those involved in the conduct of research to:
  - a. Develop mutually beneficial, sustained partnerships with existing community infrastructure, such as primary care providers and community-based organizations. These partnerships should engage in outreach and education efforts that inform the community about research beyond any particular study. Whenever possible, research sites located in the same geographic area should collaborate in these efforts.
  - b. Engage in outreach activities with community groups, particularly those working to reduce health disparities, to educate the broader community about research beyond any particular study.
  - c. Implement training for community members to prepare them sufficiently for the research related activities they will undertake.
2. Culturally and Linguistically Appropriate Standards and Clinical Trials (CLAS-ACT): Federal officials have recently underscored the need for cultural competency training in the research setting, supporting researchers to apply CLAS standards to the clinical trials process<sup>5</sup> and we agree. This training in cultural competency as it relates to study access, recruitment, and retention should enable those involved in the conduct of research to:
  - a. Implement the consent process through trained staff, including, when available and appropriate, patient navigators who can assist in the consent process at the patient's request.
  - b. Address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process, including the use of trained medical interpreters or a telephone language line<sup>6</sup> for LEP individuals, throughout the informed consent process and when consent forms are not available in the individual's native language.
  - c. Appropriately use the OHRP-approved "short form" in the consent process.

For those involved in the review or oversight of research, (e.g., IRB administrators, members), we recommend that they have a basic of understanding of these issues, as applicable to the research application under review:

1. The disease being studied, including its standard of care.
2. The research process being proposed, be it traditional clinical research, CBPR, social and behavioral research, etc.
3. Key aspects of community outreach and accessible communication and education strategies.
4. The Belmont Report and ethical requirements for research.
5. The informed consent process.

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<sup>5</sup> Culturally and Linguistically Appropriate Standards And Clinical Trials. <http://www.omhrc.gov/templates/content.aspx?ID=5046> and <http://www.bcm.edu/edict/clas-act/index.htm>

<sup>6</sup> 24-hour accessible interpretation services utilized in many health care institutions

For those involved in the review or oversight of research, (e.g., IRB administrators, members), we recommend that they be trained in these areas:

1. Strategies for community engagement in research, including CBPR.<sup>7</sup> While IRBs do consider the local context in which research is conducted, IRBs are neither expected nor required to assess the risks and benefits of a given study to participants' communities or the broader community, and most do not make this assessment.<sup>8</sup> Similarly, IRBs are neither expected nor required to assess the nature and extent of community support for the study. However, IRB examination of studies' community benefit and community support may improve overall research outcomes.<sup>11</sup>
2. Appropriate community member roles on the IRB.
3. How to consider evidence of community engagement in and community support for studies seeking IRB approval.
4. Approaches to appropriately address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process.
5. The appropriate use of the OHRP-approved "short form."

We also recommend that specific orientation, training and mentoring be provided for IRB community (non-affiliated, non-scientific) members to help ensure they are comfortable and competent in their roles on IRBs.<sup>9</sup> These members can help to ensure that language and other aspects of a research study make sense to the layperson. They can bring unique viewpoints to the IRB; nonaffiliated members are not biased by employment, and non-scientific members are not biased toward the research question.<sup>10</sup> They can play an important role in evaluating the benefits and risks to research participants, reviewing the informed consent process to ensure participant protection, reviewing protocols, and making presentations to community groups about the role of IRBs and the importance of human subjects research.<sup>11, 12, 13</sup>

There are a number of barriers to community members' participation on IRBs, including not having a clear definition and understanding of their role, and the complexity and amount of information reviewed.<sup>14</sup> Most, community IRB members, for example, view their role solely as simplifying consent forms.<sup>15</sup>

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<sup>7</sup> In January 2008, Community-Campus Partnerships for Health convened a workgroup to develop a CBPR training curriculum for IRBs and REBs. For more information, visit <http://depts.washington.edu/ccph/irbhome.html> or contact Jessie Tobin at [jtobin@mcw.edu](mailto:jtobin@mcw.edu)

<sup>8</sup> Flicker S, Travers R, Guta A, McDonald S & Meagher A. (2007). Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health*. Published Online April 10, 2007

<sup>9</sup> Schuppli CA, Fraser D. (2007). Factors influencing the effectiveness of research ethics committees. *Journal of Medical Ethics*. 33(5):294-301.

<sup>10</sup> Hurst, M. (2001). The value of difference: nonaffiliates on IRBs provide alternative views. *Protecting Human Subjects*. Summer: 1-3.

<sup>11</sup> Grignon J Wong K and Seifer SD. (2008). Ensuring Community-Level Research Protections: Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Seattle, WA: Community-Campus Partnerships for Health.

<sup>12</sup> Taylor, C. (2002). Community vs. enclave: the moral voice of community can be reflected in IRB composition. *Protecting Human Subjects*. Summer-Fall: 6.

<sup>13</sup> Anonymous. (2001). Community representation: Broadening the perspective and value base of research ethics boards. *NCEHR Commun*. 11(1):11-4.

<sup>14</sup> Wallwork, E. (2003). Failed community representation: Does the process inhibit full IRB participation by community representatives? *Protecting Human Subjects* (9):4, 14.

<sup>15</sup> Sengupta S, Lo B. (2003). The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Academic Medicine*. 78(2):212-8.

The largest study to date of non-scientific and non-affiliated IRB community members found that 47% of these individuals identified lack of education and training as a problem, and 78% wanted more intensive education and training for new members.<sup>15</sup> Many training programs already exist, listed in Appendix A (pages 5-7), that are appropriate for community IRB members. We strongly believe that it is the responsibility of the research sponsor and/or research institution to ensure the availability of such training. We outline qualification and expectations of community IRB members in Appendix B (page 8).

Building upon reports of the National Bioethics Advisory Committee and the Institute of Medicine, we also recommend that OHRP require IRBs to be comprised of 25% community (non-scientific, unaffiliated) members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.<sup>16 17 18</sup>

*B. Need for HHS development of a regulation requiring the implementation of such training and education programs*

We believe that federal regulations must help to ensure that all those who are involved in the conduct, review and oversight of research are adequately educated about, and sensitized to the protection of human subjects in the specific areas above that are missing from current requirements. Training in these areas is needed so that those involved in the conduct, review and oversight of research can (a) better understand the implications of research design and recruitment plans on goals for participation; b) better assess community benefit and relevance to a proposed study; and c) assure appropriate understanding of consent process by participants. Federal regulations should require both the implementation of training and education programs and the demonstration of competence.

**Contact Information for these Comments**

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<sup>16</sup> National Bioethics Advisory Commission. (2001). Ethical and Policy Issues in Research Involving Human Participants Bethesda.

<sup>17</sup> Institute of Medicine. (2003). *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary*. The National Academies Press; Washington, D.C.

<sup>18</sup> Additional guidelines for community IRB members can be found on page 28 of the IOM report: Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary. <http://www.iom.edu/CMS/3740/4881/12889.aspx>

## **Appendix A: Training Resources for IRB Members**

We recommend that HHS consult and utilize these training resources when developing and implementing training requirements for IRB members, in particular community IRB members. Although a number of these resources are focused on cancer clinical research, we believe they are more broadly applicable.

### **NCI's CARRA Training Program**

This NCI training program helps patient advocates become effective participants in the NCI peer review process. The 2 ½ day workshop curriculum is for members of its Consumer Advocates in Research and Related Activities (CARRA) program. Entitled “Preparing Consumer Advocates to Participate in Peer Review,” the training program focuses on the scientific, technical, and cultural aspects of NCI peer review and how advocates can more effectively represent the collective views of survivors, patients and family members during the grant review process. Each workshop is conducted by a multidisciplinary training team, which includes consumer advocates, university scientists, NCI staff, and training facilitators. Mock peer reviews are also conducted to demonstrate how grant applications are reviewed and scored, and how advocates address human subjects concerns during the peer review process. The NCI website includes a downloadable version of the CARRA training curriculum and additional training resources for community representatives/patient advocates. <http://carra.cancer.gov/members/training/overview>

### **Coalition of Cancer Cooperative Groups' Patient Advocacy Training**

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

[http://www.cancertrials-help.org/patient\\_content/pdMainContent.aspx?intAppMode=5](http://www.cancertrials-help.org/patient_content/pdMainContent.aspx?intAppMode=5)

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

The Research Advocacy Network's Advocate Institute provides advocates with multiple learning modalities so they can better understand the medical research system, participant protections and scientific concepts for more effective interactions with the research world. The Advocate Institute offers on-site training programs, as well as web-based learning opportunities, including the “SkillBuilders” and “ScienceBuilders” on-line training courses.

<http://www.researchadvocacy.org/advocateInstitute/index.php>

### **American Association for Cancer Research (AACR) Scientist ↔ Survivor Program**

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

### Project LEAD

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

[http://www.stopbreastcancer.org/index.php?option=com\\_content&task=view&id=395&Itemid=138](http://www.stopbreastcancer.org/index.php?option=com_content&task=view&id=395&Itemid=138)

### C3 Research Advocacy Training Program

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

<http://fightcolorectalcancer.org/>

### NCI's Cancer Information Service Partnership Program

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

<http://cis.nci.nih.gov/>

### Project TRES

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

<http://projecttres.sdsu.edu/tres/about.jsp>

### NCCTG Patient Advocate Symposium

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

<http://ncctgpatientadvocates.org/home.html>

### Community-Campus Partnerships for Health Curriculum on Developing and Sustaining CBPR Partnerships

This evidence-based curriculum is intended to develop a deeper understanding of the basic principles of CBPR and strategies for applying them. The curriculum includes seven units, each containing learning objectives; in-depth content information about the topic(s) being presented; examples and interactive exercises; and citations and suggested resources, selected based on their relevance and usefulness to the unit's learning objectives.

<http://www.cbprcurriculum.info>

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

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

<http://apps1.jhsph.edu/cochrane/CUEwebcourse.htm>

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

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

[http://www.sporeadvocates.net/content/index.php?option=com\\_frontpage&Itemid=1](http://www.sporeadvocates.net/content/index.php?option=com_frontpage&Itemid=1)

For other training resources, contact Deborah Collyar, president of PAIR: Patient Advocates In Research and former SPORE PART program director, at [collyar@att.net](mailto:collyar@att.net), for other training resources.

### Cancer Information and Support Network (CISN)

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

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

<http://cisncancer.org/>

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

Family Health International’s (FHI) Office of International Research Ethics (OIRE) has developed a curriculum to empower community representatives to participate effectively in research activities. Developed and field-tested in eight countries, the Research Ethics Training Curriculum for Community Representatives (RETC-CR) helps community representatives to understand the research process and their roles and responsibilities as partners of the research team. The curriculum also explains the corresponding roles and responsibilities of ethics committees/IRBs and researchers. The RETC-CR addresses universal principles of research ethics, informed consent, ethics committees, and other important issues. The curriculum is available in an on-line, self-study version, as well as in print and CD-ROM format. Available languages include English, French, Spanish and Portuguese.

<http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm>

## **Appendix B: Suggested Qualifications<sup>19</sup> & Expectations of Community IRB Members**

*From: Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH). (2008). Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy. Silver Spring, MD and Milwaukee, WI.*

- Being directly affected by cancer (personally, as a caregiver, or as a member of community disproportionately affected), AND
- Having experience with cancer advocacy through activities/organizations<sup>20</sup> that go beyond a personal experience, AND
- Willing to learn more about cancer, cancer research, and how cancer affects the community
- Meaningful connection with a specific constituency affected by cancer with which he/she is able to have ongoing communication and feedback
- Genuine understanding of the specific community's/constituency's' needs
- Interest and ability to network with other organizations with an interest in cancer
- Level of comfort articulating opinions assertively and professionally among persons of all types of educational and professional backgrounds
- Interest/ability to listen, reflect, question, and respond without becoming defensive or confrontational
- Interest in gaining self-confidence to ask questions of physicians/scientists, and to disagree with them when necessary
- Ability to interact effectively with clinical and laboratory researchers
- Ability to discern the needs of the community from which they came and the needs of local research studies

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<sup>19</sup> Qualifications are not limited to educational achievement, as measured by an academic degree

<sup>20</sup> As may be demonstrated by geographic residence or place of work, connection to the disease, trial participation, or use of a particular health service