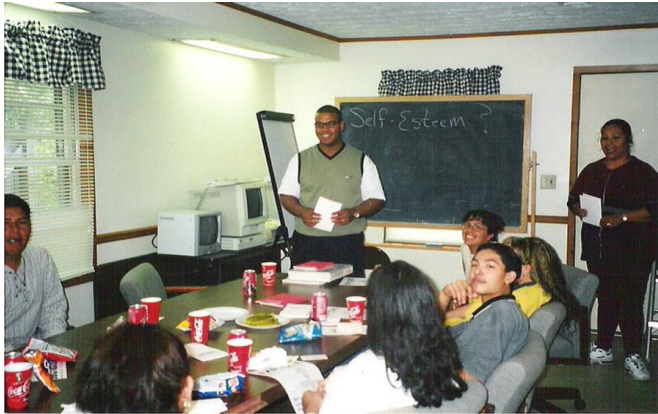


# Enhancing Community Involvement in the IRB Process

*Stacy Collins, Education Network to Advance Cancer Clinical Trials*  
*Sarena D. Seifer, Community-Campus Partnerships for Health*  
*Eric Wat, Special Service for Groups*





# Agenda

- Introductions and Feedback
- Why Involve Community in the IRB Process
- Lessons Learned from a Community IRB
- Enhancing Community Involvement in the IRB Process: Strategies and Resources

*Fill out contact list and we'll send you slides & other resources related to this session*



# Why Involve Community in the IRB Process?

1. What is an IRB and What Purpose Does it Serve?
2. **Highlighting the Importance of the IRB Member**
3. Community-Based Participatory Research Proposals and the Human Subjects Review Process: Methods for Working with University IRBs
4. Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board
5. Beyond the University IRB: Understanding Alternative Models for Human Protections, Part II: Creating an Independent Community IRB - When is it Right for You?
6. IRB Reform: Changing Policy and Practice to Protect Communities



# Why Involve Community in the IRB Process?

- Community members can play important roles in:
  - Evaluating benefits and risks to research participants
  - Reviewing informed consent process to ensure participant protection
  - Reviewing protocols
  - Helping to ensure that language and other aspects of a study make sense to the layperson
  - Making presentations to community groups about the role of IRBs and the importance of human subjects research



# Orientation & Training are Critical

The largest study to date of non-scientific and non-affiliated IRB community members found that although 94% of participants had positive experiences working with scientist IRB members, 88% occasionally had been intimidated and felt disrespected by them. 47% identified lack of education and training as a problem, and 78% wanted more intensive education and training for new members.

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.



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

National strategic planning effort co-sponsored by Community-Campus Partnerships for Health & the Education Network to Advance Cancer Clinical Trials

Core funding from the Agency for Healthcare Research and Quality and the National Cancer Institute #1-R13-HS016471, 2006-2009

Details at [www.communitiesaspartners.org](http://www.communitiesaspartners.org)

# Issues the Project Seeks to Address

Trial participation among adult cancer patients remains at about three percent.

- This rate is even lower among people of color and the medically underserved, who tend to have higher cancer mortality rates than the population as a whole.

The low accrual rate in therapeutic cancer clinical trials has a profound effect on

- the quality of research
- the rate new scientific discoveries are made
- our ability to provide quality care to all.

# Project Purpose

To bring together a diverse group of stakeholders to explore ways to improve Phase III cancer treatment trials, utilizing the principles & approaches of community-based participatory research.

To develop a national strategic plan for research, practice & policy for incorporating CBPR principles & approaches into Phase III cancer clinical trials.

# Who Represents “Community”?

*Communities as Partners in Cancer Clinical Trials developed these definitions in the context of the project:*

*Community representatives* have experience with the healthy population at risk and ideally are affiliated with a community-based organization or group whose constituency is disproportionately affected by cancer.

*Patient advocates* have experience as a patient with cancer, caregiver or family member and ideally are affiliated with a cancer advocacy organization or group

Orientation, preparation and training is critical

# Seven Recommendation Areas

- I. Ensure Meaningful Role for Community Representatives and Patient Advocates in Trial Design
- II. Ensure Community Perspectives in IRB Review Process**
- III. Improve Informed Consent Process
- IV. Ensure Community Perspectives in Protocol Development, Trial Design and Implementation
- V. Improve Participant Recruitment, Accrual and Retention
- VI. Enhance Local Community Support for Cancer Research
- VII. Enhance Community Interpretation, Dissemination and Implementation of Trial Outcomes

## II. Ensure Community Perspectives in the IRB Review Process

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

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

*...and that the AAHRPP incorporate these into its accreditation standards for IRBs.*

## **II. Ensure Community Perspectives in the IRB Review Process**

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

4. Include evidence of community engagement in and community support for the study. Be comprised of 25% community IRB members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.



# Lessons Learned from a Community IRB

See Eric Wat's slide presentation at

[http://depts.washington.edu/ccph/pdf\\_files/Tran\\_and\\_Wat\\_presentation.pdf](http://depts.washington.edu/ccph/pdf_files/Tran_and_Wat_presentation.pdf)



# Strategies & Resources

## **Sources for community members who can serve on IRBs:**

Community partners of community-based research projects that have been previously approved by the IRB

NCI's CARRA (Consumers in Research and Related Activities)

Program: <http://carra.cancer.gov>

CCPH: <http://www.ccph.info>

Community-Based Public Health Caucus of APHA: [www.apha.org](http://www.apha.org)

National Community Committee of the CDC Prevention Research Centers: <http://www.cdc.gov/prc>

Board members from local community-based organizations



# Strategies & Resources

## **Educational resources for community IRB members:**

*You Want to be an IRB Community Member...Now What?"*

published by USC: <http://www.usc.edu/admin/provost/oprs>

Community IRB Website and Listserv sponsored by the Human Subjects Research Program at the U.S. Department of Energy:

<http://www.ornl.gov/communityirb/default.htm>

Audio-files, handouts and proceedings from CCPH's Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research:

<http://depts.washington.edu/ccph/irbcalls2.html>



# Strategies & Resources

## **Educational resources for community IRB members:**

Public Responsibility in Medicine & Research: <http://www.primr.org/>

Online research ethics curriculum for community health workers, promotores and others working in culturally diverse communities: <http://projecttres.sdsu.edu/tres/>

Online research ethics curriculum for community representatives: [www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm](http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm)

National Alliance on Mental Illness' online training guide for members who serve on IRBs: <http://www.nami.org>



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- Sengupta S, Lo B (2003). The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Acad Med* 78(2):212-8.
- Also see the June 2008 issue of the Journal of Empirical Research on Human Research Ethics, devoted to theme of ethical considerations in community-based participatory research: <http://ucpressjournals.com/journal.asp?j=jer>

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