



*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

# **Trainer Manual**

*for Community Advisory Boards*

**Module 1**  
Community Participation  
in Research

Version 1.0 – May 2007



## MODULE 1: COMMUNITY PARTICIPATION IN RESEARCH

### Proposed Agenda\*

**Opening Activity: “We Know More than We Think We Do”** (30 minutes)

**Part I Slides and Discussion** (60 minutes)

**Activity: Research Team Panel** (45-60minutes)

**Part II Slides and Discussion** (60 minutes)

**Activity: Small Group SWOT Analysis** (60 minutes)

**Participant Evaluation** (15minutes)

*\*Modules may be divided and adapted to fit the available time frame, to meet the specific needs of individual CABs, and to provide adequate break time for participants and trainers. Please adapt the participant evaluation forms so that they are appropriate for the training plan.*



## OPENING ACTIVITY

### Module 1

#### “We Know More Than We Think We Do”

---

Time frame **(30-35 minutes)**

#### Purpose

This exercise can help participants have fun while teaching each basic information about HIV and HIV clinical research, and can help participants realize gain confidence that they “know more than they think they do”.

#### Materials needed

- For each team: 3 signs, 1 that say “Always True,” 1 that says “Sometimes True” and 1 that says “Never True”
- Statements list (Suggested statements are provided below.)
- Small game prizes for all (optional)

#### Instructions

- Divide the group into teams. Teams should have at least 3 people, but not more than 6 people.
- The trainer reads the statements one at a time. Use simpler or more complex statements depending on how experienced or knowledgeable you think the groups may be. You should have about 4 statements per number of groups of participants (For example, if you will have 3 groups, prepare 12 statements).
- Have the groups discuss for about two minutes whether the statement is always, sometimes, or never true.
- Then ask the groups to hold up the sign that reflects the answer they have chosen.
- Have a brief discussion on the reasons for the choice each group made.
- Explain the correct response (if it has not yet been explained by one of the groups), taking time to mention the reasons why a group might have selected one of the other responses.
- Give small “prizes” to all of the teams at the end of the game (optional).

#### Suggested statements

*(You may add or subtract from these statements as necessary.):*

- A pregnant woman with HIV infection will give birth to an HIV-infected infant. (Sometimes true)
- HIV stands for “Human Immunodeficiency Virus” (Always true)

- A person can transmit HIV to another person without HIV by sneezing or coughing around them. (Never true)
- A person is infected with HIV but is not sick. (Sometimes true)
- A person can be put on experimental medicine without their knowledge. (Never true)
- AIDS stands for “Acquired Immunodeficiency Syndrome” (Always true)
- Pregnant women are not allowed to participate in research/clinical trials during pregnancy. (Sometimes true)
- An infant that breast feeds from an HIV positive mother will become HIV infected (Sometimes true)
- HIV attacks the immune system. (Always true)
- Clinical trials are for people who have no other access to treatment. (Sometimes true)
- If you say “no” to participation in a clinical trial, your doctor can decide to stop taking care of you. (Never true)
- CAB stands for “Community Advisory Board” (Always true)
- Once a person signs a consent form to participate in a study, he/she cannot change his/her mind. (Never true.)
- A person cannot be enrolled in a clinical trial without their consent (Always true)
- Community members are experts on the needs and concerns of their community (Sometimes true)



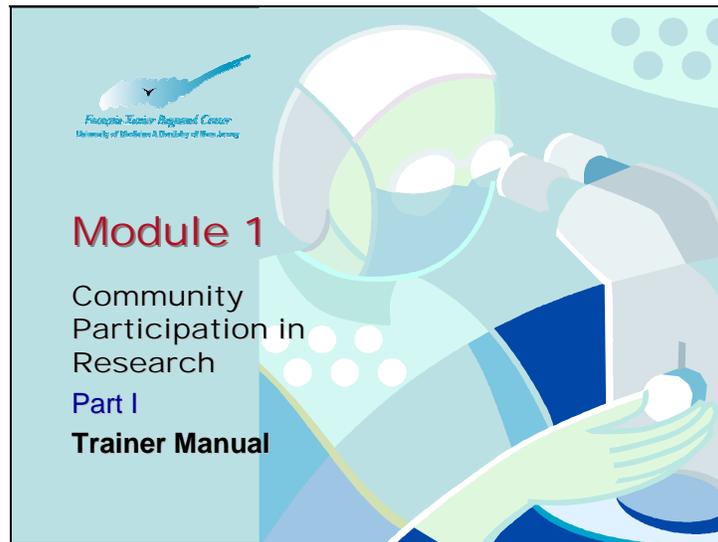
# **Module 1**

## **Part I Slides - Insert Here**





Slide 1



## Slide 2

This teaching tool was developed by the François-Xavier Bagnoud Center at the University of Medicine and Dentistry of New Jersey, with the support of the International Maternal Pediatric and Adolescent Clinical Trials (IMPAACT) network.

Excerpts from this publication may be reproduced or adapted with acknowledgement of the source, provided the material reproduced by and for non-profit distribution only.



Claire Schuster, BS, MPH  
Network Community Coordinator  
Social & Scientific Systems, Inc.  
EMail: [cschuster@ss-3.com](mailto:cschuster@ss-3.com)  
(301) 628-3319



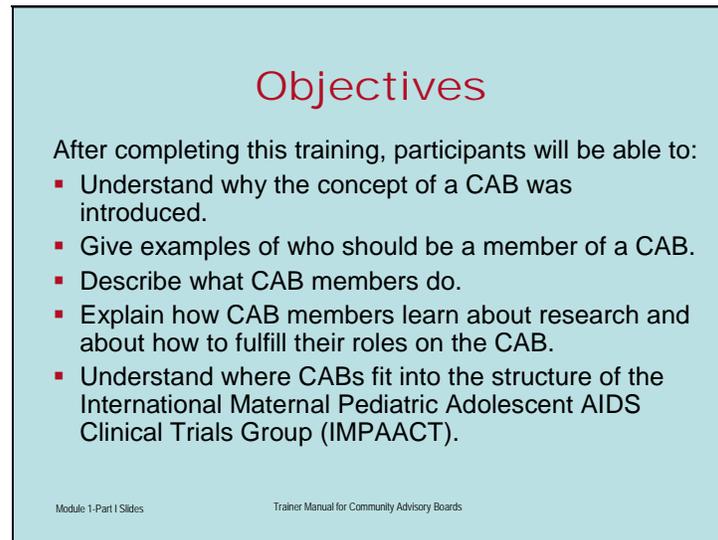
*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

Mary Jo Hoyt, RN, MSN  
IMPAACT Global Training Director  
François-Xavier Bagnoud Center  
EMail: [info@fbcenter.org](mailto:info@fbcenter.org)  
(973) 972-9230

**Version 1.0 – May 2007**

Module 1-Part I Slides                      Trainer Manual for Community Advisory Boards

## Slide 3



The slide is a light blue rectangle with a black border. At the top center, the word "Objectives" is written in a red, sans-serif font. Below it, the text "After completing this training, participants will be able to:" is followed by a bulleted list of five objectives. At the bottom left, it says "Module 1-Part I Slides" and at the bottom center, it says "Trainer Manual for Community Advisory Boards".

## Objectives

After completing this training, participants will be able to:

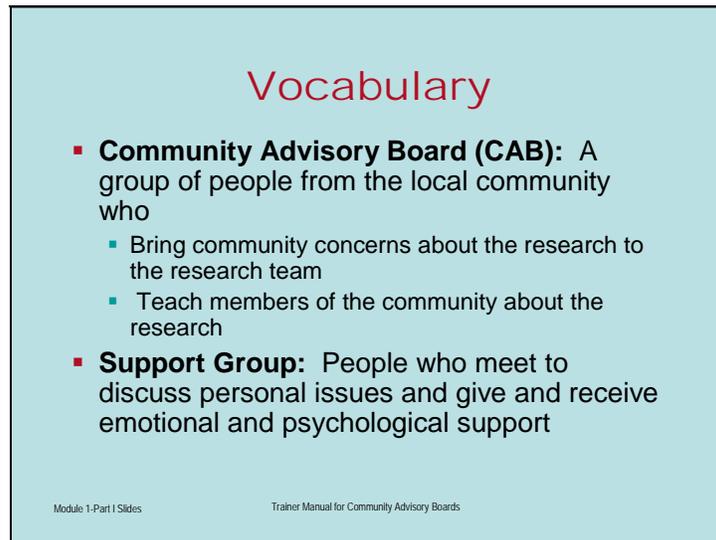
- Understand why the concept of a CAB was introduced.
- Give examples of who should be a member of a CAB.
- Describe what CAB members do.
- Explain how CAB members learn about research and about how to fulfill their roles on the CAB.
- Understand where CABs fit into the structure of the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT).

Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

This slide lists the objectives (or goals) for today's program. The slides we will show and the activities planned for this training all relate to these questions:

- How did the concept of a CAB begin? What is the history of the movement to involve the community in scientific research?
- What exactly do CAB members do? What is the **mission** of the CAB and what role do members play in this?
- Where do community representatives and CABs fit within the organizational structure of the IMPAACT? Do CAB members really have a voice in how research is done?
- Who should be a member of a local CAB? Do you need to have research experience?
- How do CAB members learn how to fulfill their role as members of the CAB? Is training provided? Is this a **volunteer** (unpaid) position, or are CAB members paid? How is the CAB funded?

## Slide 4



**Vocabulary**

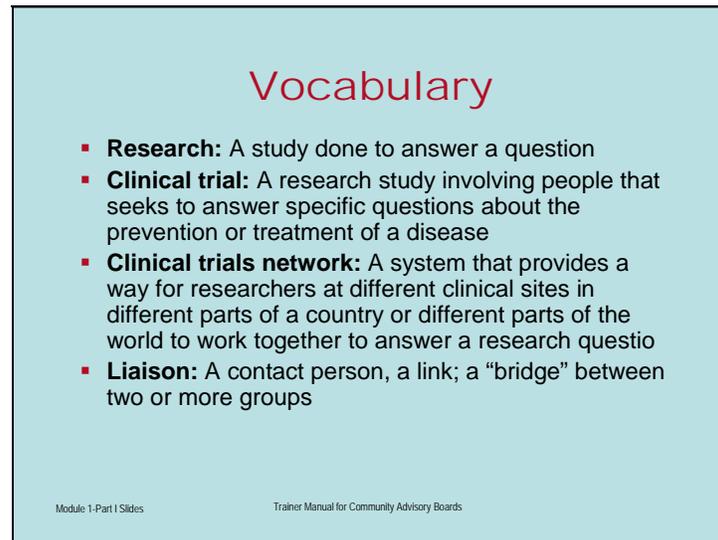
- **Community Advisory Board (CAB):** A group of people from the local community who
  - Bring community concerns about the research to the research team
  - Teach members of the community about the research
- **Support Group:** People who meet to discuss personal issues and give and receive emotional and psychological support

Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

This training is about the role of a **Community Advisory Board** in clinical research. A Community Advisory Board, called a “**CAB**”, plays a role in the planning and implementation of **clinical trials**.

- Briefly, a CAB is a group of people who bring community concerns about the research to the researchers, and teach members of the community about the research. The CAB serves as a point of communication and education between researchers and the community members who may be affected by the research.
- Because CAB members for HIV research often have been personally impacted (directly or indirectly) by HIV, people sometimes confuse CABs with a support group. However, a **support group** is more personal, and does not have an impact on research or an interest in working with the community.
- The CAB and the support group do not have the same function.

## Slide 5



**Vocabulary**

- **Research:** A study done to answer a question
- **Clinical trial:** A research study involving people that seeks to answer specific questions about the prevention or treatment of a disease
- **Clinical trials network:** A system that provides a way for researchers at different clinical sites in different parts of a country or different parts of the world to work together to answer a research question
- **Liaison:** A contact person, a link; a “bridge” between two or more groups

Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

A clinical trial is a research study that involves studying a new treatment for a health problem in people. The treatment might be something to prevent, improve, or cure a disease. Examples are treatments for HIV, or for the complications of HIV like pneumonia or TB. The overall purpose of doing clinical research is to improve health care.

Clinical trials are often performed in the context of a research network. A clinical trials network is a system that provides a way for researchers at different clinical sites in different parts of the world to work together to answer the same research question. To do this, the research team at each site follows the same research plan.

At times during this training, we will use the word “**liaison**”. A liaison is a person who serves as a link between two or more people or two or more groups.

## Slide 6

## Discussion question

How do you think HIV research or HIV care could benefit from community input into planning and implementing clinical trials? General examples?



Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

If you could say anything you liked to the people who are in charge of our clinic (or hospital), what would you like to tell them to do to improve the service they provide here?

Thinking about these things from your perspective is exactly the idea of a CAB. In this instance, we are talking about community members giving feedback on how research is done (rather than clinical care). Your point of view counts and can make a difference in how things are done!

Talking about how the community feels about things is a situation in which community members are the experts (not the scientists).

**Trainer:** You might want to start the discussion by providing one example of your own. If you don't want to provide one of your own, then here are some simple examples that could be used: 1) Ex: Clinic visits are very time consuming. Clinical trials that require more clinic visits than what is considered "normal" are going to be very problematic for patients unless we are able to improve the amount of time people are waiting to see the doctor or nurse, and then waiting again to make the next appointment and to receive the prescriptions. This will affect enrollment in clinical trials, and also has a negative impact on clinic attendance and adherence to care. 2) Ex: The community is very concerned about researchers "experimenting" on their children. The CAB wants to enlist the help of all of the research team in providing more education about clinical trials, and about the safeguards in place to protect participants in research.

## Slide 7

## What is a clinical trial?

- Planned **study** involving people
- The goal of a clinical trial is to find a better way to prevent or treat a disease.

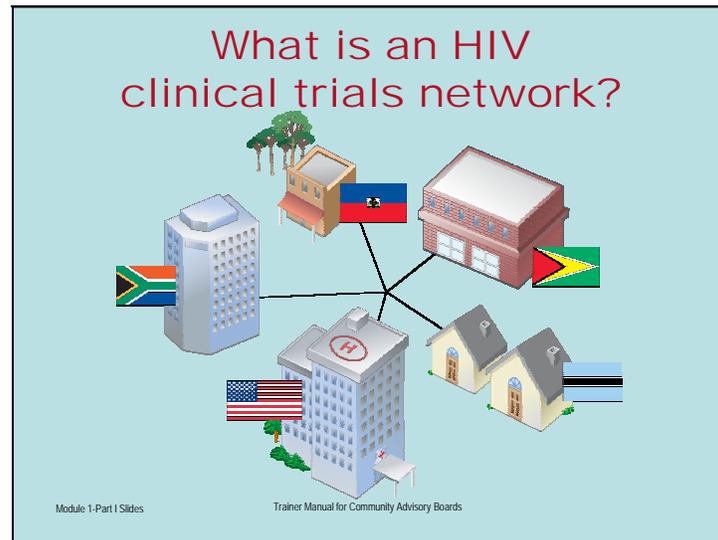


Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

Before speaking more about CABs, it is important that all of us understand a little bit about clinical trials and research. As we noted in the beginning, a **clinical trial** is research with people, which is designed to answer a question about a health problem. For example, here is an example of a common type of clinical trial. The research question is: “Can this new medicine prevent or control this disease?” For a more specific example: If a pregnant woman with HIV infection takes this medicine during labor, will this new medicine lower the risk that her infant will be infected with HIV?

- Clinical trials are the fastest and safest way to find effective and safe treatment for a health problem.
- Clinical trials are conducted after a medicine has been shown to be safe and potentially effective in the laboratory and in animals. There are all kinds of clinical trials going on right now to help different kinds of health problems.
- This training is about clinical trials for the prevention and treatment of HIV infection.

## Slide 8



- When new medicines or other treatments are tested in clinical trials, it is important that they be tested in many people to learn if the medicine is effective and that it is safe. With a very big health problem like HIV, where there are many people affected all over the world, and many different researchers working, it is also important that researchers be able to work together. When researchers from different places work together on clinical trials, this helps bring the knowledge of many different people together to improve health care.
- As we said earlier, a **clinical trials network** is made up of researchers from hospitals and clinics in different areas of one country or different parts of the world who cooperate to answer the same research question.
- This way, people at many different hospitals and clinics can be a part of the same clinical trial.
- Each clinic in the research network is called a **clinical trials unit (CTU)** or **clinical trials site (CTS)**.
- Doctors in charge of research at each CTU are called **principal investigators**.

## Slide 9

**What is IMPAACT?**

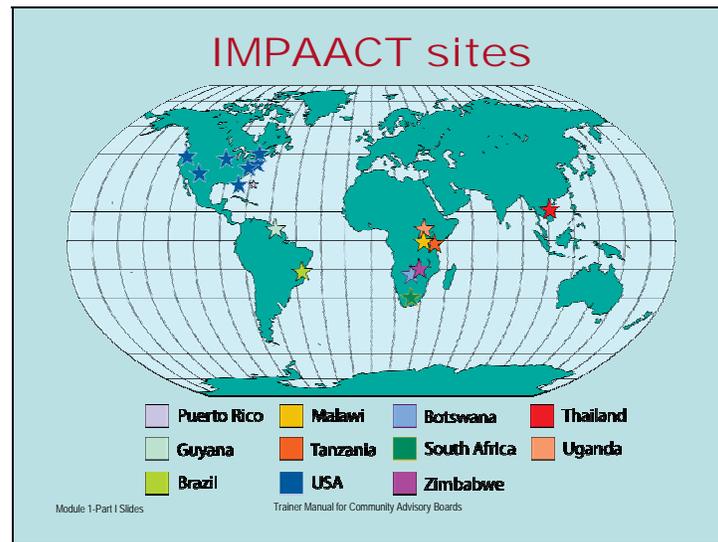
- **IMPAACT** is the International Maternal Pediatric Adolescent AIDS Clinical Trials Group. It is the name for this HIV clinical trials network.



Module 1-Part 1 Slides      Trainer Manual for Community Advisory Boards

- Many CTUs working together are called a **network**.
- **IMPAACT** is the name of the HIV clinical trials network in which we (at this site) are working. This site (**Trainer:** give name of your site) is a clinical trials unit within the IMPAACT network. This network is made up of investigators from around the world who work together on clinical studies focusing on HIV in pregnant women and in infants, children, and teenagers. (If your site is involved with other networks, you may wish to name them here)
- The goal (or **mission**) of IMPAACT is to significantly decrease the sickness and death associated with HIV infection in these groups. The US Government, through the **National Institutes of Allergy and Infectious Disease (NIAID)** and the **National Institute of Child Health and Development (NICHD)**, funds this research network, as well as funding at least 5 other research networks that focus on different issues in the HIV epidemic (such as adult infection, prevention of HIV infection, and development of an HIV vaccine).
- You may have heard of the **Pediatric AIDS Clinical Trials Group (PACTG)**, which was a US-based network. The PACTG existed for over 15 years, and much of what we know about prevention of mother-to-child transmission of HIV, treatment of pregnant women with HIV, and treatment of HIV in infants and children has come from the PACTG clinical trials.
- Over the years, PACTG evolved to become an international network; PACTG has been re-organized and is now called the International Maternal Pediatric and Adolescent Clinical Trials network, or IMPAACT.

## Slide 10



- This slide shows the places where IMPAACT sites are located. In the continents shown on the map, pregnant women, infants, children, and teenagers with HIV are taking part in clinical research and trying to find answers that will improve care and treatment.
- A couple of examples of clinical trials we have done at this site (or are doing or plan to do at this site) are (Trainer: describe 1-2 local or regional studies. Ask the Principal Investigator at your site for help if needed).

## Slide 11

## Linking sites in the network

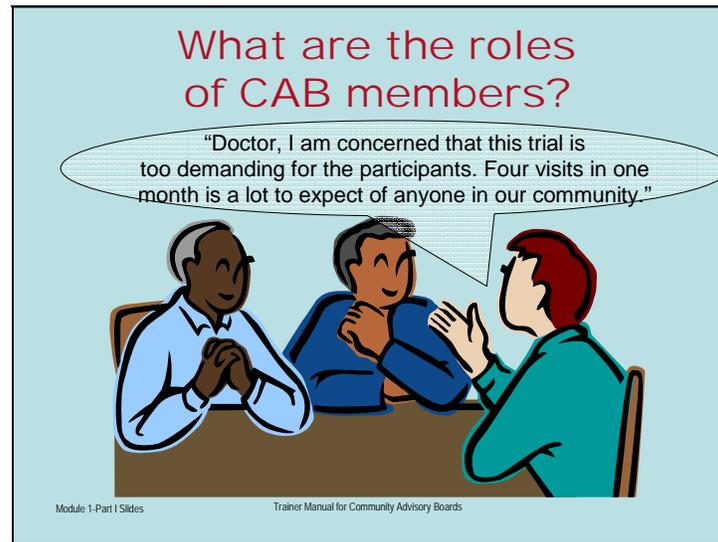
- The work of the network is largely done by committees and by protocol teams
- These groups often “meet” by phone



Module 1-Part I Slides Trainer Manual for Community Advisory Boards

- You may wonder how the work of a world-wide research network gets done. Much of the work is done by committees or teams of network members. For example, once an idea for a new study is approved by the leaders of the network, a **protocol** team is formed to develop the protocol, which is the written plan for the study
- To get their work, the committees and teams often meet by phone.
- IMPAACT also has a large group meeting (usually in Washington, DC) when all researchers and other network team and committee members from around the world come together in one place, at least once per year. This meeting includes representatives from the community, and protocol teams also normally include an experienced community representative.

## Slide 12



As we said earlier, community participation in research is provided through the formation of committees called Community Advisory Boards or CABs.

One role of CAB members is to serve as a communication link (**liaison**) between the community and the researchers. In this slide, the CAB member who is the liaison to the local research team is telling team members that a part of the study plan may be too demanding for the participants.

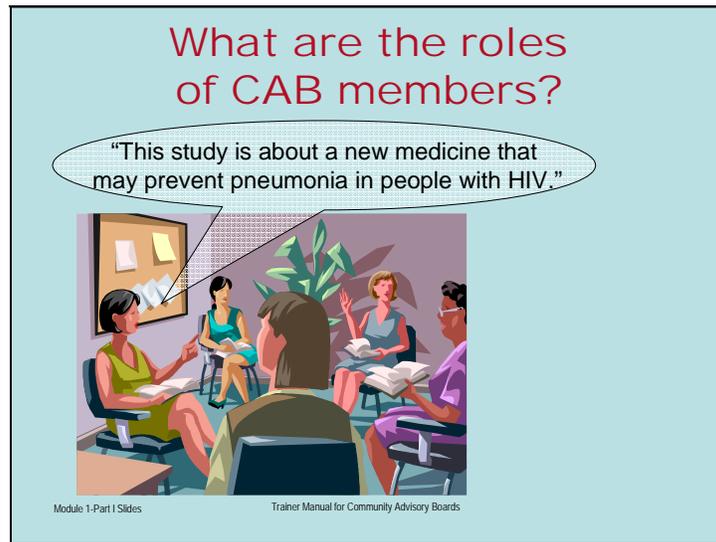
As a liaison, a CAB member's role includes:

- Checking that the research seems fair to those who participate in the research and the larger community
- Telling the researchers the needs, ideas, questions, and opinions of the community of people affected by HIV
- Encouraging the researchers to respond to the community's questions and concerns.

In the role of liaison to the research team, the local CAB member is an **advocate**, a person who speaks on behalf of the community.

Another role of CAB members is to assist researchers with planning the trial and doing the research.

## Slide 13



- Another role of CAB members is to share with the community information about the ongoing work of the research team and about the results of the research. This information will come from the investigators to the CAB members, and from the CAB members to the community.
- For example, CAB members may bring an explanation of the research protocol to the community and ask questions designed to facilitate getting community members to voice their thoughts or suggestions or opinions about the study or about research in general.
- If community members have strong negative reactions or ask for specific changes to a protocol, those reactions must be respectfully considered by the investigators. This is important in order for research to have the maximum benefit for all.

## Slide 14

Who should be a member of a CAB?



- CAB members
  - Stakeholders
  - Community volunteers

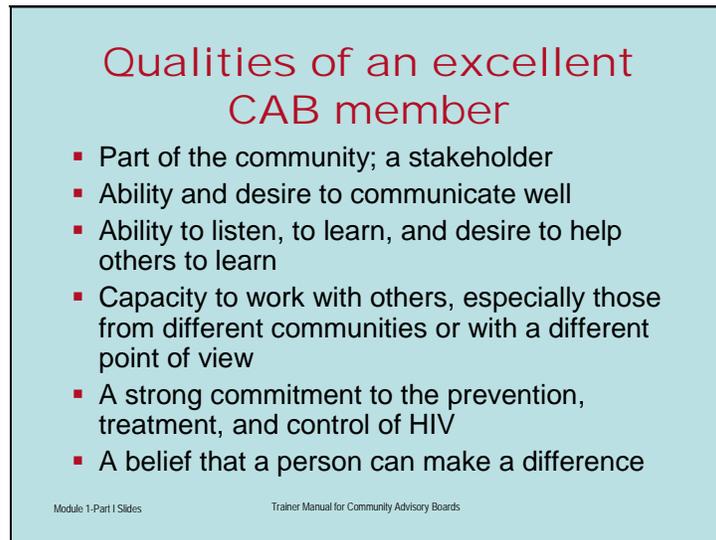
Module 1-Part I Slides  
Trainer Manual for Community Advisory Boards

CAB members are people who:

- Have a direct interest in HIV and its prevention or treatment. People who have a direct interest or involvement are often referred to as **stakeholders**.
- Live in the geographic area where the research is being done and/or
- Are infected or affected by HIV and live in the geographic area (such as family members, people at risk for HIV; people with HIV; caregivers of someone with HIV); or
- Have influence in the community where the research is being done (such as a member of the clergy, political leader, director of HIV-related service organization, members of the non-research health care community).

Every local CAB makes its own decisions about who will be a member of the CAB based on the judgment of the existing CAB members about what types of characteristics and skills best represent the community and the mission of the CAB.

## Slide 15



### Qualities of an excellent CAB member

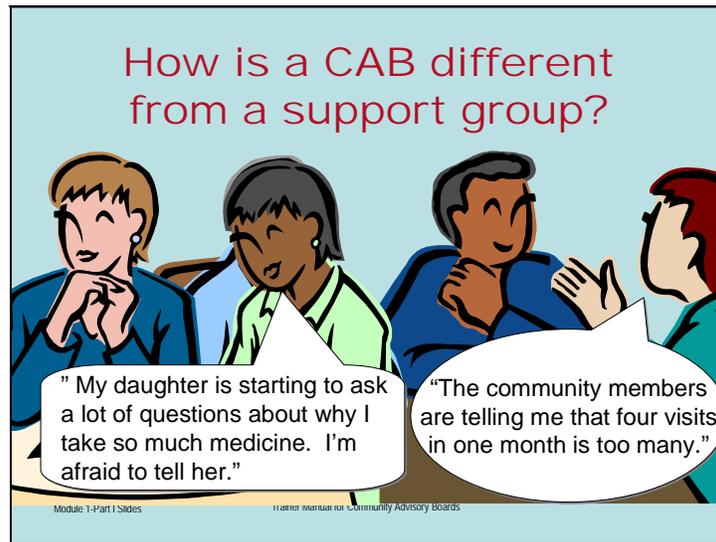
- Part of the community; a stakeholder
- Ability and desire to communicate well
- Ability to listen, to learn, and desire to help others to learn
- Capacity to work with others, especially those from different communities or with a different point of view
- A strong commitment to the prevention, treatment, and control of HIV
- A belief that a person can make a difference

Module 1-Part I Slides

Trainer Manual for Community Advisory Boards

- It is important that individuals who want to work with the CAB know their community, and also understand that many diverse groups within their community (such as youth, women, gay men, injection drug users, etc.) are impacted by HIV, and that these groups must work together for the best outcome.
- CAB members can be taught about research and about HIV disease and treatment, but the ability to listen, the desire to learn, and the desire to help others understand research and HIV should be qualities that CAB members bring to the group.
- Above all, CAB members must have a strong commitment to the prevention and treatment of HIV, a belief that community involvement is important, and a belief that the community can make a difference in the lives of people who have HIV or who are at risk for HIV infection.

## Slide 16



This slide is meant to clarify again what the difference are between a support group and an HIV Community Advisory Board. In the past, there has sometimes been some confusion about this.

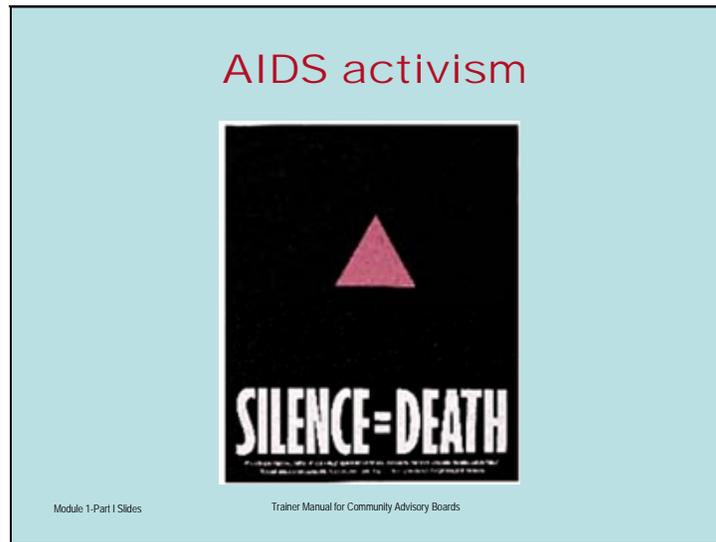
- A support group is a gathering of people who meet to discuss how HIV *personally* affects them or their family. At meetings, people learn about and share ideas on how to cope with having HIV. They learn to give and receive emotional support. As you can see on the slide, the women on the left are discussing a very personal issue related to disclosure of HIV status.
- The CAB members' work is about the whole community, not individual, personal problems. The picture on the right side of the slide shows a CAB member suggesting that the number of clinic visits required by the study is too high for some people in his community.

## Slide 17



- Have decisions about medical research always included the community? No, not at all. Community participation in research relatively recently, in the early years of the HIV epidemic. It was the beginning of the HIV epidemic in the U.S. that sparked community members affected by HIV to insist that they be given an official role within research networks and protocol teams so as to be heard by researchers and by government agencies funding HIV research and care. At that time, very little was known about HIV disease, and there was no treatment available. People directly affected by HIV were at very high risk of death and so they had very good reason to demand that decision-making about HIV research and care include people with direct interest in the outcome.
- In 1989 a group of activists, uninvited, marched into a clinical trials network meeting in Washington, DC. The activists demanded they be permitted to attend the meeting so they, as stakeholders, could give researchers their opinions and share their concerns. The communities hit hardest by HIV infection did not want research on HIV to go forward without hearing from the people with HIV. The activists wanted a voice in where money was spent, how research ideas were prioritized, and how protocols were written and conducted. They did not feel that the government, the researchers, or others could understand the issues involved without hearing from the very people with the most to gain or lose by the decisions being made. So the idea for creating Community Advisory Boards was born in 1989, and the roles and responsibilities of CABs have evolved (changed, grown) over time, all over the world.

## Slide 18



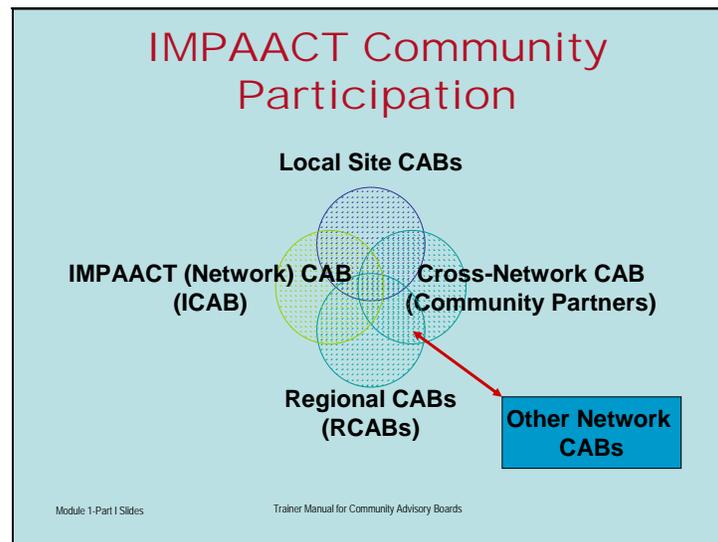
- Does anyone remember this picture (logo)? This is the logo of a group called ActUp, an activist group formed in response to the HIV epidemic in the United States. The goal of ActUp is to speak out, to pressure the government, the pharmaceutical companies, and investigators to do what needs to be done in the best interest of people with HIV. That includes studying new medicines for people with HIV and including people infected or affected by HIV in planning and doing the clinical trials.
- Trainer: Discussion question: In this logo, what group's silence are we focusing on? And if this group remains silent, why is death the end result?

## Slide 19



- This activism eventually led to the establishment of Community Advisory Boards (CABs). CABs are now a way people of the community can work together with researchers and the research team. Working together is also called “collaboration.”
- CAB members are not scientists, and are not expected to understand research in the same way as a scientist. The very valuable knowledge CAB members bring to the research team is knowledge of the community.
- The movement to include community in the research process has been slowly evolving over the last 20 years. But at this point, community advisory boards are a requirement for every HIV clinical trial unit funded by the U.S. government, and community advocacy groups are common worldwide.

## Slide 20



In the IMPAACT Research Network, the structure of community participation has been set up in this way (note graphic):

- Locally, each clinical trials unit at a hospital or clinic forms its own CAB.
- IMPAACT is also working on the development of **regional CABs** (called **RCABs**). RCABs are to be made up of representatives from some or all of the local CABs in the **region** (for example, northeastern U.S. or sub-Saharan Africa)
- Regional CABs will select a member or members to serve on the “**IMPAACT CAB**” (called **ICAB**), which is often referred to as the “network CAB”. The members of the ICAB will be some of the most experienced CAB members; they will be the leaders of the community participation effort and will have direct communication with all of the IMPAACT executive leadership.
- Finally, some members of the ICAB will represent IMPAACT on the cross-network CAB **Community Partners**. This CAB includes people from different U.S. government-funded HIV research networks such as IMPAACT, the AIDS Clinical Trials Group, and the HIV Vaccine Clinical Trials Group.

## Slide 21

## Local CABs

- Share information and advise the site research team
- Share information, report to, and educate the community



Module 1-Part 1 Slides      Trainer Manual for Community Advisory Boards

At every clinical trial site, community representatives should be part of the research team—this is now a requirement. The local CTU CAB serves many purposes, most importantly:

Sharing information and advising the site's research team about

- The research needs and concerns of the local community
- How to best communicate with the local population(s)
- Identifying possible links to the local population (for example, community centers, NGO or AIDS service organizations)

Sharing information, reporting back to and educating the community about

- Research projects being proposed
- About the value of the research to/in the community
- About the results of completed clinical trials and what the results mean for clinical care

## Slide 22

**Discussion question**

What are the local organizations or agencies that would be the most likely places we could interact with community members?



Module 1-Part 1 Slides      Trainer Manual for Community Advisory Boards

*Discussion question:* What are the local organizations or agencies that would be the most likely places we could interact with people in our area to discuss research and HIV?

## Slide 23

## Local CABs

- CAB members also educate *each other* about the needs and concerns of their communities.

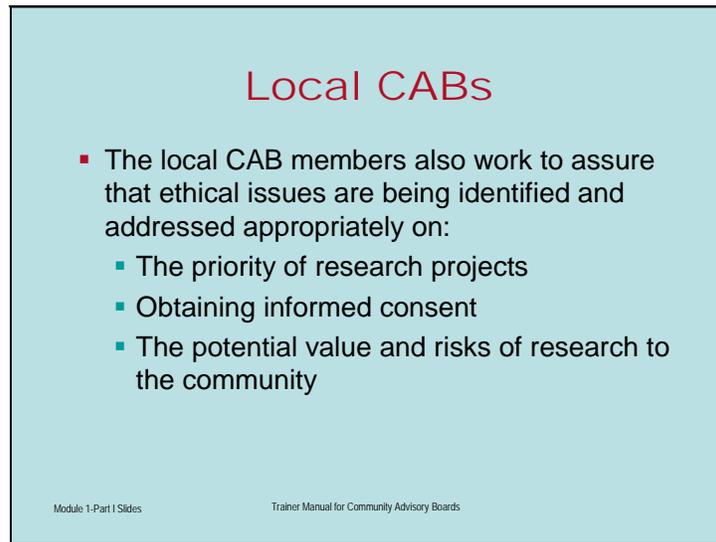


- Members of a CAB are not necessarily all from the exact same community

Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

- In addition to educating the research staff about the research needs of the community and educating the community about the value of the research, community advisors also must educate one another about the groups within the community they represent.
- Even when CAB members are from the same basic geographic location, they may be part of different groups within the community. For example, are the needs of an HIV+ teenager the same as those of a grandmother caring for an HIV infected orphan infant? Are the needs of men the same as the needs of pregnant women? Does a community leader, such as a religious leader with influence in the community, know everything he needs to know about pregnant women, sex workers, or what it means to care for a child with HIV? Of course not! No one can claim knowledge of all groups at risk of or impacted by HIV, so CAB members must share their knowledge in order to develop the most complete knowledge base possible.
- It's important to think about groups within your community, and to work to avoid creating stigma or discrimination within the CAB by excluding groups from representation on the CAB who are stakeholders in the IMPAACT research agenda.

## Slide 24



**Local CABs**

- The local CAB members also work to assure that ethical issues are being identified and addressed appropriately on:
  - The priority of research projects
  - Obtaining informed consent
  - The potential value and risks of research to the community

Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

Local CAB members also work to assure that ethical issues are being identified and addressed related to:

- The priority of research projects: Is it more important to find a way to protect infants exposed to HIV via breastfeeding that to find a way to prevent sexual transmission of HIV with a microbicide or a vaccine? Who decides? Should the community have a voice in the decision when all “important” research can’t be launched at the same time?
- Obtaining informed consent: Is the research team making sure that people who volunteer for a study really understand the study and the potential risks and feel secure in the knowledge that participation is entirely voluntary? Do CAB members feel that the consent document is written in a way that is understandable to most people in their communities?
- The potential value and risks of research to the community. The potential benefit to participants in the study, and the potential benefit to the community, must be greater than the potential risks of the study to either participants or the community as a whole.

## Slide 25

## Discussion Question

- **Case Study:**
  - Two communities
- Evaluate the possible risks vs. the possible benefits of a clinical trial for 2 different communities. Which community should participate in the study?



Module 1-Part I Slides      Trainer Manual for Community Advisory Boards

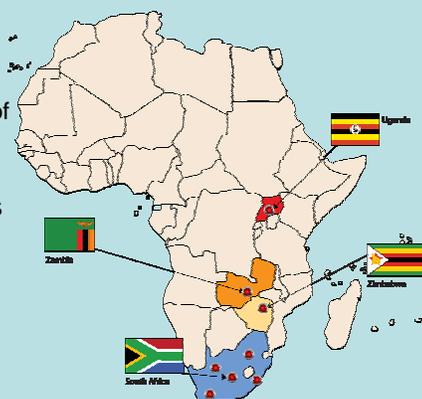
Weighing the risks of a study vs. the potential benefits can be complicated, but not always. To practice this, let's imagine this case study:

- A new ARV has been discovered that seems to improve the CD4 count and viral load in the few people in which it has been tested. It needs to be studied in more people. Researchers know that there is a small risk that some people will have a serious allergic reaction to the medicine, but they believe that overall the medicine is safe and likely to be effective. IMPAACT research sites are deciding whether or not their site will participate in the study.
- At one CTU, if the medicine is proven to be safe and effective by the trial, then the government can be expected to pay for the medicine for anyone who needs it once the study is completed. At a different CTU research site, resources are limited and the government will not be able to pay for the medicine once the study is completed, and so the medicine will only be available to the very few people who can afford to buy it.
- **Discussion question:** Are the potential benefits and risks at these 2 sites the same? **Post discussion suggested comment to reinforce the concept of risk : benefit ratio:** Why should a community that will derive very little benefit from the medicine after the study is complete expose its community members to the risks involved in testing an experimental medicine?

## Slide 26

### Regional CABs (RCABs)

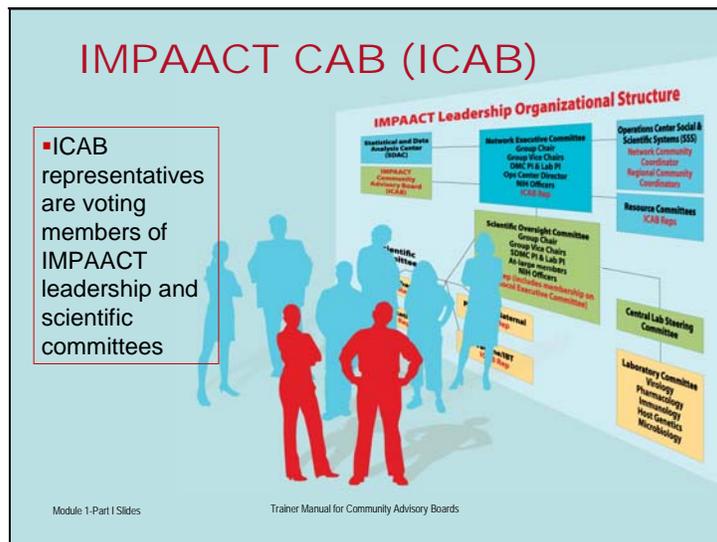
- Study
  - Awareness of research clinical trials
- Provide ideas
- Develop relationships
- Mentors and trainers



The map shows three regions in Africa highlighted with colored boxes and their respective national flags: Zimbabwe (green and white), Uganda (black, yellow, and red), and South Africa (green, white, and blue). The map is titled 'Regional CABs (RCABs)' and includes a list of functions: Study (Awareness of research clinical trials), Provide ideas, Develop relationships, and Mentors and trainers. The map also includes the text 'Module 1-Part I Slides' and 'Trainer Manual for Community Advisory Boards'.

- Regional CAB members study community awareness of research and clinical trials, and study the educational needs of the community related to clinical trials and research.
- Like the members of local CABs, they provide ideas about how best to recruit and keep trial participants in the study.
- They work to develop relationships among sites in the region so resources and information can be shared.
- Regional CAB members may also serve as mentors and trainers for local CAB members.
- The regional CAB can do something like the exercise that we will do later in this training program---called a "SWOT" analysis. This is an opportunity for CAB members from the region to share ideas and solutions regarding the strengths, weakness, opportunities, threats of their CABs (SWOT). This helps them to use each others' ideas and successes and to develop a supportive network among the local CABs in the region.

## Slide 27



- ICAB members focus on providing information to network leaders about community concerns and priorities related to the HIV epidemic and HIV research. There are ICAB representatives who are members of the Network Executive Committee, the Scientific Oversight Committee, and many of the science and support committees where this important communication can happen—direct communication with the network investigators and leaders who plan the research program for IMPAACT.
- The ICAB learns about community concerns and priorities through communication with regional and local CABs on conference calls and at group meetings where the representatives can speak with each other about local and regional issues relevant to the research and how the research is conducted. It is very helpful to the whole system of CAB representation for the local CAB to try to regularly communicate the issues faced at their site with ICAB representatives.

## Slide 28

The slide is a light blue rectangle with a black border. At the top center, the title "IMPAACT CAB (ICAB)" is written in a bold, red, sans-serif font. Below the title, there is a bulleted list of five items, each starting with a red square bullet. The text is in a black, sans-serif font. At the bottom left of the slide, there is small text that reads "Module 1-Part I Slides". At the bottom center, there is small text that reads "Trainer Manual for Community Advisory Boards".

### IMPAACT CAB (ICAB)

- ICAB representatives join protocol teams to speak to the team about things like:
  - The risks and potential benefits of the protocol
  - The design of the study
  - What is expected of participants who join the study
  - Who can join the protocol and who is not allowed to join
  - Whether the informed consent document is clear and understandable

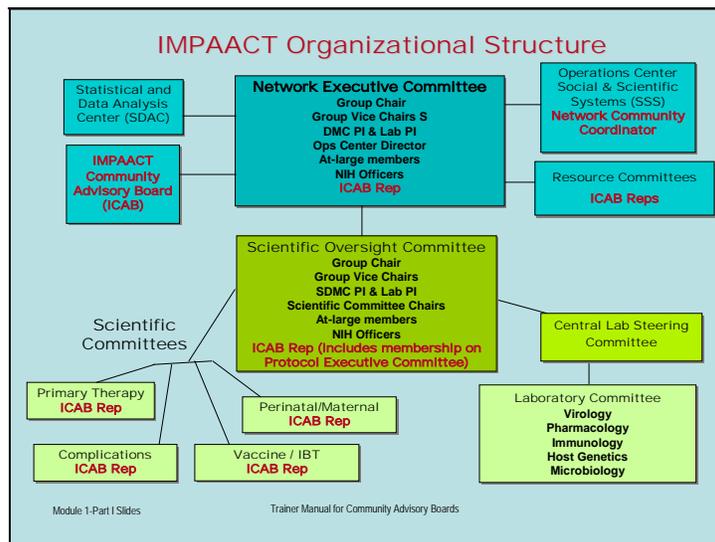
Module 1-Part I Slides

Trainer Manual for Community Advisory Boards

We will talk more about protocol teams and how CAB representatives function within the team in a later module, but here we briefly describe the CAB role. There is a “protocol workbook” available that can help CAB members understand a protocol and contribute their expertise in a knowledgeable way.

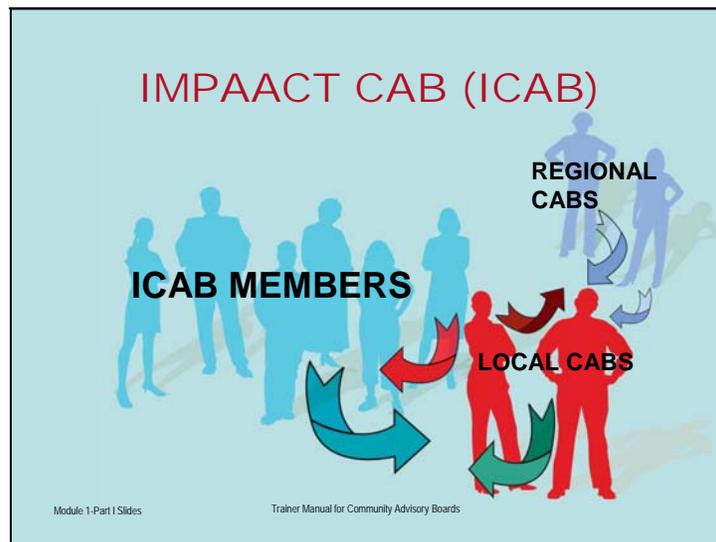
- Having community representatives on protocol teams is an important way for the community to influence the way the protocols are developed. For example, experienced community representatives can make judgments about whether the potential benefit of the protocol is worth any potential risk associated with the research. Community representatives can also judge whether the expectations of the study for participant visits and tests is overly burdensome for members of the community.
- Community representatives carefully evaluate the rules for study participation to make sure no one is refused entry to the study unless its really necessary.
- Community members are the experts at judging whether the informed consent document (which explains all about the study) is clearly written in language that community members can understand. If not, the community representative may be able to suggest language that would be better understood by people in his or her community.

## Slide 29



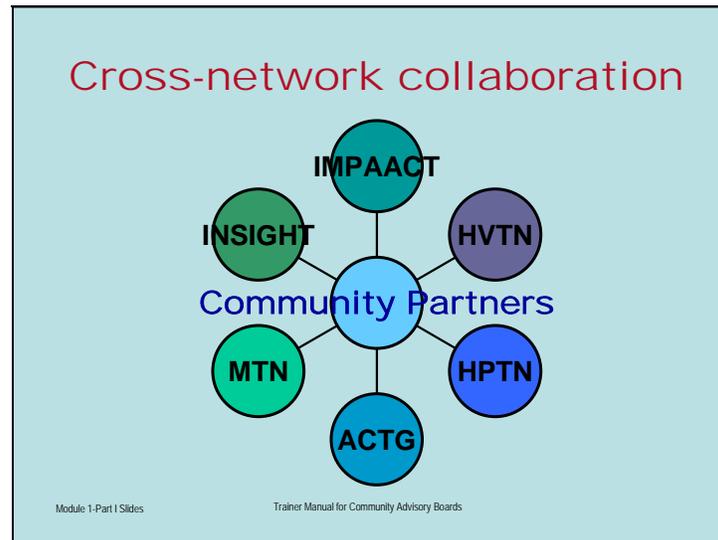
- This is a picture of how the IMPAACT network is organized. We will review this in more detail in another training module, but for this picture shows the areas where ICAB representatives participate in the committees where protocols are developed and where decisions about the are made.. (Trainer: Please note these areas in slide)
- **The scientific committees are shown on the lower left portion of the slide.** These committees are where protocols are “born.” Ideas for a study start within these committees, and each committee has an ICAB representative as a member..
- **Scientific Oversight Committee (SOC):** The members of this committee must review and approve ideas for protocols, deciding which protocols will be done, and which will be rejected. There are many reasons why a protocol may be rejected, including expense/lack of funding, or not considered a high priority, or that the idea is being developed or addressed by a different protocol, or that the science is not good. CAB representatives will base their support or non-support for a protocol on whether or not the community feels it is a priority, fits the mission, is a good use of resources, and is “do-able” in IMPAACT communities.
- **Network Executive Committee (NEC):** Has the responsibility for review and final approval of the budgets, protocols and many other aspects of running the network. ICAB representatives on the NEC are the voice of the community at the highest decision-making level of the network.

## Slide 30



- ICAB members are the most experienced community representatives within the network, and they have generally been the recipients of a significant amount of training to prepare them for their roles. As such, their job is to share that knowledge by helping to prepare or make available education and training for CABS and provide CABS with up to date information about what is happening within IMPAACT.
- Part of education and training is to help members of regional and local CABS gain the knowledge needed to participate in network activities. For example, the ICAB may prepare training programs to help CAB members learn the necessary information to participate in a protocol team. In addition, an ICAB member may serve as a **mentor** for a CAB member who is participating in a network committee or protocol team for the first time.

## Slide 31



Yet another level of community participation!

As mentioned earlier, there are several HIV research networks funded by the U.S. government in addition to IMPAACT. Community representatives from *different* networks want to *keep each other informed* of the work of their network.

- IMPAACT community representatives (usually ICAB members) participate in a new group called “**Community Partners.**” Community Partners will consist of community representatives from all of the HIV research networks funded by **NIH** (through the **Division of AIDS**). Other research networks, for example, are the **HIV Vaccine Trials Network**, the **HIV Prevention Treatment Network**, the **Microbicide Trials Network**, and the **Adult AIDS Clinical Trials Group**.
- The creation of Community Partners will allow the community groups from all of the different HIV research networks to share information and to promote effective representation of the communities impacted by HIV clinical trials in a cohesive and comprehensive way. In this way, they are considered the “**cross-network**” community representatives.

## Slide 32

## Summary

- IMPAACT is a **clinical trials network**.
- **Community representatives** are part of the research network organizational structure at the local, regional, international and cross-network level.
- In general, community representatives function as **liaisons** between their communities and the research teams and as expert **advisors** to researchers in matters related to community.
- Community representation is a vastly important but relatively new concept in clinical research

Slide 33



Please see the trainer instructions, “Discussion: Experts from the Field,” and “Suggested Questions for Experts”.

# RESEARCH TEAM PANEL

## Module 1

Time frame **(30-60 minutes)**

### Purpose

This exercise will give participants a chance to hear about community participation in research from experienced CAB members and and/or other members of the research team. This will be an opportunity to hear true stories and about CAB activities, that will make the information from the slides and exercises more concrete.

### Materials needed

- Flipchart and marker (or blackboard and chalk) for note taking (optional)

### Instructions

Before the training the trainer should invite 3-6 CAB members and/or other members of the research team to participate in the discussion as panel members. You may also consider inviting a willing research participant if desired.

- Explain to the panel members that this is an introductory training on the role of community participation in research, and that you would like them to be prepared to tell stories and give information about CAB activities.
- Provide the panel members with a list of questions that you (as the panel moderator) may ask the panel. (See last page.)
- Ask the panel members from the research team to be prepared to share stories about situations when community participation was (or could be) particularly valuable.

### During the discussion

- Seat the panel members together where all participants can see them. If possible, seat the panel members close to the audience to encourage conversation and interaction. (Avoid seating them on a stage or dais above or far away from the audience. This tends to be overly formal and may block conversation.)
- Begin by explaining the purpose of the discussion to participants. Tell participants that they are encouraged to interact with the panel by asking questions of the panel members and commenting on the discussion.
- Explain that discussion is meant to be informal. Tell the panel members a little bit about the audience. Or, if the audience is small, ask participants to introduce themselves.
- Thank the panel members for coming, and then ask each member to introduce himself or herself.

- Begin the conversation by asking the panel members (or one particular expert) a question. (See list later on this page) *The questions for the panel members provided here are suggestions only. You may add your own questions, and should let the participants direct the questioning whenever possible.*
- Skills for facilitating an informal discussion
  - Summarize the important points made after an expert answers a question
  - Offer a comment on the panel members' answers
  - Use encouragers when participants ask a question or make a comment, such as "You've raised a good point." "Thank you for that important question." "I'm glad you asked that." or "I'm glad you said that; it's very interesting."
  - Consider asking the panel members or participants to respond to each others' comments. For example: "What do the rest of you think about what she said?" "Can other panel members comment on this?"
  - Try to get the conversation "on topic" if it is drifting too far from the purpose of the discussion. Gentle coaxing such as "That's interesting, but let's try to get back to discussion." or "Let's save that question for later in the day, and stay with the discussion of community involvement while the panel members are here with us."
  - When the time for ending the discussion comes, notify the participants and the panel members with a comment like "Let's take one more question." or "Just a couple more comments and then our time is up."
- Thank the panel members for their time and their input, — and the participants for their input as well —and end the session with applause.
- If time allows, re-cap the important points made during the panel discussion.

### Suggested questions for discussion

#### **For CAB members:**

- Can you tell us a little bit about some of the things that you do as a CAB member?
- Can you share with us some reasons why you joined the CAB, and why you are still participating as a CAB member?
- What are your thoughts about the value of community participation in research?
- What kind of preparation for your role did you have before you joined the CAB? What training have you had since you have joined?
- Do any of the CAB members have other responsibilities within IMPAACT or another research network (such as participating in a network committee or protocol team), in addition to being a member on the local CAB?
- What responsibilities would you like to see the CAB have in the future?
- What projects would you like to see the CAB work on in the future?

***For non-CAB members:***

- What is your role on the research team?
- How do you think the research team can be helpful to the CAB? How do you think the CAB members are or could be helpful to the research team?
- Can a research team member (or a CAB member) give us an example of when you think a CAB member made a difference? Or any times when you think a CAB member could have made a difference, had someone been available?
- What responsibilities would you like to see the CAB have in the future?
- What projects would you like to see the CAB work on in the future?
- Is there anything you can suggest to the participants that might help them prepare for being a member of the CAB?



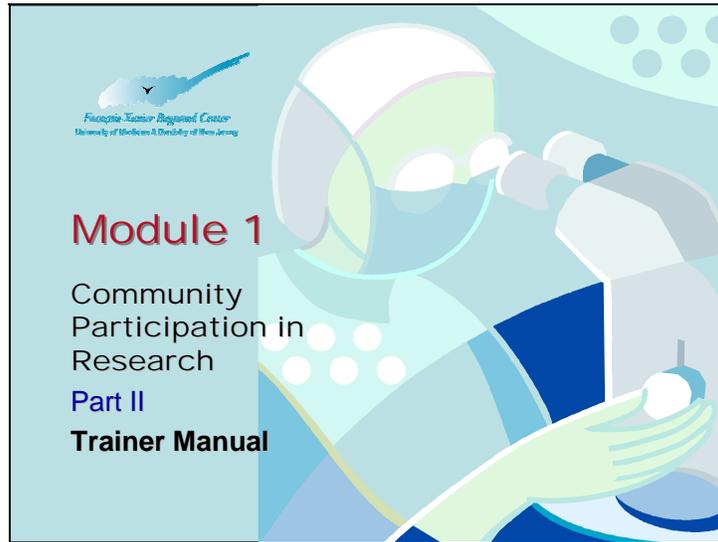
# **Module 1**

## **Part II Slides - Insert Here**





Slide 1



## Slide 2

This teaching tool was developed by the François-Xavier Bagnoud Center at the University of Medicine and Dentistry of New Jersey, with the support of the International Maternal Pediatric and Adolescent Clinical Trials (IMPAACT) network.

Excerpts from this publication may be reproduced or adapted with acknowledgement of the source, provided the material reproduced by and for non-profit distribution only.



Claire Schuster, BS, MPH  
Network Community Coordinator  
Social & Scientific Systems, Inc.  
E-Mail: [cschuster@ss3.com](mailto:cschuster@ss3.com)  
(301) 628-3319



*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

Mary Jo Hoyt, RN, MSN  
IMPAACT Global Training Director  
François-Xavier Bagnoud Center  
E-Mail: [info@fxbcenter.org](mailto:info@fxbcenter.org)  
(973) 972-9230

**Version 1.0 – May 2007**

Module 1-Part II Slides Trainer Manual for Community Advisory Boards

## Slide 3

## Review

- Group Discussion:
  - What is the purpose of community participation in research?
  - Who are CAB members?
  - What is the role of a CAB member at a (local) CTU?
  - What are the levels of CAB participation in the IMPAACT network?



Module 1-Part II Slides Trainer Manual for Community Advisory Boards

**Trainer:** You may want to do a brief review of the material covered in Part I of the training, especially if considerable time has past since Module 1 Part I was presented. It's helpful to do this review as a discussion with the group, rather than giving answers yourself.

## Slide 4

**Who are CAB members?**

People living with HIV, parents, and caregivers and other people knowledgeable and concerned about HIV.

- Volunteers from the community with broad range of backgrounds

Module 1-Part II Slides      Trainer Manual for Community Advisory Boards

For local CABs within IMPAACT, members of the community advisory boards are **volunteers** from the community. A volunteer is a person who does a job or participates in a program without being paid. Volunteers for the CABs should come from a broad range of backgrounds and represent different groups in the community. CAB members typically include:

- People living with HIV, including pregnant women and adolescents
- Parents and caregivers of people living with HIV
- People who know about HIV, science, and/or health
- Community members concerned about making life better for their friends and neighbours
- Community leaders or other community members who may be in a position to support the goals of the CAB

Once a few willing people are identified by the research team to begin the group, the CAB can make more decisions on what qualities and characteristics they want in new members. These decisions will eventually become one of the policies (rules) of the CAB. In another of the training modules, we talk more specifically about how to recruit members for your CAB, and how to keep members interested in the work of the CAB.

## Slide 5

**How are CAB members prepared for their role?**

**Training**

- Basics of research
- Understanding research protocols
- HIV disease and treatment
- Ethics of research
- Rights of study participants
- Skills for being a CAB member
- Skills for listening and teaching in the community

Module 1-Part II Slides      Trainer Manual for Community Advisory Boards

- All CAB members come to their work with different backgrounds, education, and experience. Not all CABs, and not all CAB members, will need the same level of training to participate in the CAB. A “Training Needs Assessment” tool is available for the CAB to use to identify the training needs of CAB members.
- CAB members must have training so that they have a basic and correct understanding of:
  - HIV
  - HIV treatment
  - How research is done
  - How to perform their roles (such as **peer** education)
- While it is the responsibility of each of the Principal Investigators at the local CTU to ensure enough training is available to support the work of the CAB, there are training materials available from the ICAB that can help support training at the sites. Additionally, training will be offered regionally and internationally.
- When training is offered for a region, or at a group meeting in the US, local CABs are usually asked to send a representative. The representative is then expected to share the information from the training with the members of the local CAB. Funding to participate in regional or international training programs is often limited, so availability may vary from year to year and from site to site depending on circumstances.
- Providing training is a requirement that allows CAB members to perform the responsibilities expected of them. In addition, it is very helpful in retaining the interest of CAB members, who can see that CAB participation has increased their knowledge and skills.

## Slide 6

How are CAB members prepared for their role?

- Mentoring: Experienced and inexperienced members work side-by-side.



Module 1 Part II Slides  
Trainer Manual for Community Advisory Boards

- **Mentoring** is another important part of developing knowledgeable CAB members. Mentoring means having experienced and knowledgeable CAB members give advice, support, and information to less experienced CAB members. New CAB members are often paired with experienced CAB members for a period of time ranging from weeks to a year, depending on the specific needs of the individual.
- Suggested mentoring activities may include: reviewing IMPAACT structure and function, utilizing these training modules for individual training, reviewing a protocol or an informed consent form together, teaching about how to run a meeting, develop a meeting agenda, or take meeting minutes, etc. The CAB may benefit from putting together an informational packet about IMPAACT and about the CAB as one method of helping to orient new members of the CAB.

## Slide 7

## Building a local CAB

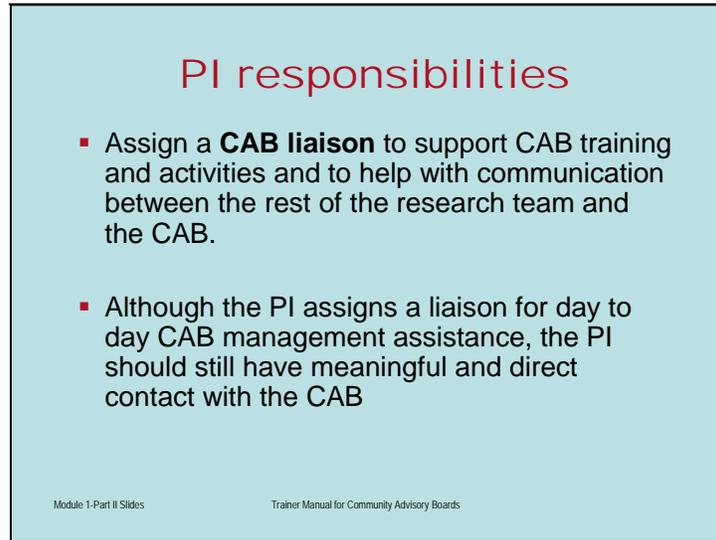
- Mission statement
- Purpose and goals
- Structure and function



Module 1-Part II Slides Trainer Manual for Community Advisory Boards

- When a CAB is just starting, it can seem difficult to know how to organize and get started. The ideas we discussed previously about the purpose of community involvement in research are not a set of instructions about exactly what you do as a group and as individual CAB members. So where do you begin -- as a CAB and as individual members? The items on this slide are starting points CAB members can use to begin making decisions about the purpose of the CAB and how it will function.
- A bit later in today's training, we will discuss writing a mission statement, choosing CAB purposes and goals and how to develop a CAB structure.
- Once a CAB has identified specific goals and work to be done, it will help determine the types of new members needed for the CAB. For example, if the CAB wants to educate families about the research program, they may seek a member who is involved in a community service organization or nongovernmental organization (NGO). This member can provide access to families who may not know about research and tell the families about the chance to enroll in a clinical trial to get treatment.
- It is important to remember that because each community is different each CAB will be different. That is why only the CAB members can decide the purposes and goals of the local CAB, and there are no specific rules to follow in setting up a local CAB. This way, the local CAB members can determine what will work the best for the CAB in their unique community. Nevertheless, if you are having difficulty starting a CAB at the local site, advice and assistance can be obtained from established CABs in other locations, the regional CAB in your area, or the ICAB. In addition, you should be able to obtain help from your own research team.

## Slide 8



The slide is titled "PI responsibilities" in red text. It contains two bullet points. At the bottom left, it says "Module 1-Part II Slides" and at the bottom center, it says "Trainer Manual for Community Advisory Boards".

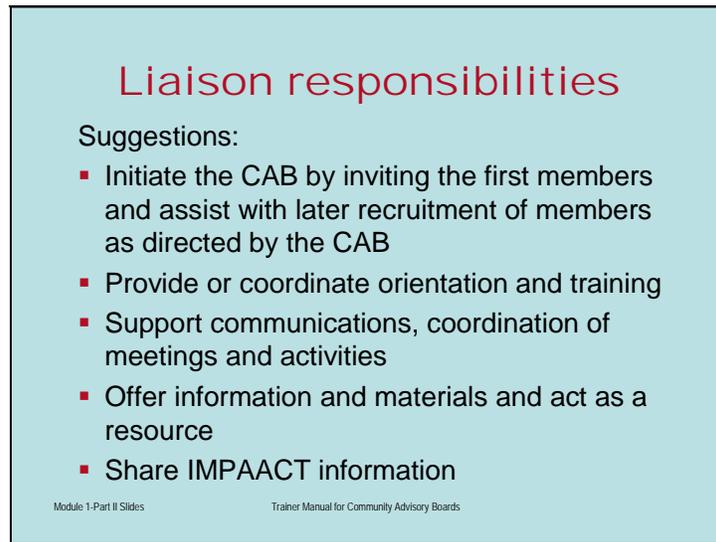
### PI responsibilities

- Assign a **CAB liaison** to support CAB training and activities and to help with communication between the rest of the research team and the CAB.
- Although the PI assigns a liaison for day to day CAB management assistance, the PI should still have meaningful and direct contact with the CAB

Module 1-Part II Slides      Trainer Manual for Community Advisory Boards

- To work effectively a CAB needs the support of the research team, beginning with the support and involvement of the Principal Investigator (PI) at the research site. The PI sets the tone for the community's involvement with the team by supporting and assisting the CAB.
- A main goal of local community participation in research is to have community members be involved in making sure that the clinical trials meet the needs of the local community. To accomplish this, the CAB needs to have direct communication with the PI, who has the ultimate responsibility for how the research team will set up and manage the clinical trials at the site.
- One of the first tasks of the PI for the CAB will be to choose a member of the research team to be the **liaison** between the research team and the CAB. This is a research team member responsible to initiate CAB and support ongoing activities and to assist with communication between the rest of the research team and the CAB)
- Nevertheless, the PI cannot give all responsibility for working with the CAB to a liaison. The PI must:
  - Attend periodic CAB meetings according to the policies of the local CAB.
  - Provide expert advice.
  - Provide information on clinical trials available and trials in progress.
  - Provide "vision" for the site.
  - Listen and respond to community concerns.

## Slide 9



### Liaison responsibilities

Suggestions:

- Initiate the CAB by inviting the first members and assist with later recruitment of members as directed by the CAB
- Provide or coordinate orientation and training
- Support communications, coordination of meetings and activities
- Offer information and materials and act as a resource
- Share IMPAACT information

Module 1-Part II Slides      Trainer Manual for Community Advisory Boards

- A member of the research team will serve as the team's **liaison** to the CAB, as discussed on the previous slide. Not only does the liaison identify and invite the first few CAB members, but the liaison often:
  - Helps to provide orientation and training
  - Helps to coordinate communications (mail and phone calls)
  - Helps to plan meetings and activities
  - Assists with recruiting additional CAB members.
  - Provides material support as needed (e.g. computer access, stationery, meeting room)

The extent of the role of the liaison should be determined by the CAB members, in collaboration with the site PI. Sites may vary in the level of responsibility given to staff as opposed to members.

## Slide 10

## Mission Statement

- A broad statement about the purpose of the CAB that describes
  - **Whom** does the CAB serve?
  - **What** does the CAB do?
  - **How** does CAB accomplish its goals?



Module 1-Part II Slides

- CABs are successful when the members work together to make decisions and accomplish goals.
- A good first step for a newly-formed CAB is to discuss and develop a **Mission Statement**. A mission statement is a broad statement about the CAB's purpose. The statement should answer these questions:
  - Whom does the CAB serve?
  - What does the CAB do?
  - How does the CAB accomplish its goals? (in general terms)

Samples of local mission statements are provided with these training materials, in the appendices.

## Slide 11

**Local CAB  
Mission Statement Sample**

- The mission of the Community Advisory Board (CAB) is to integrate community into the clinical trials site in order to advance HIV/AIDS research to meet the needs of medical science and the needs of infected and affected children, adolescents and their families in this community

Module 1-Part II Slides Trainer Manual for Community Advisory Boards

This is a sample of one local mission statement.

## Slide 12

## CAB goals and objectives

**Goal:** Aim or purpose  
*Example: “To educate families attending the clinic about research and clinical trials”*

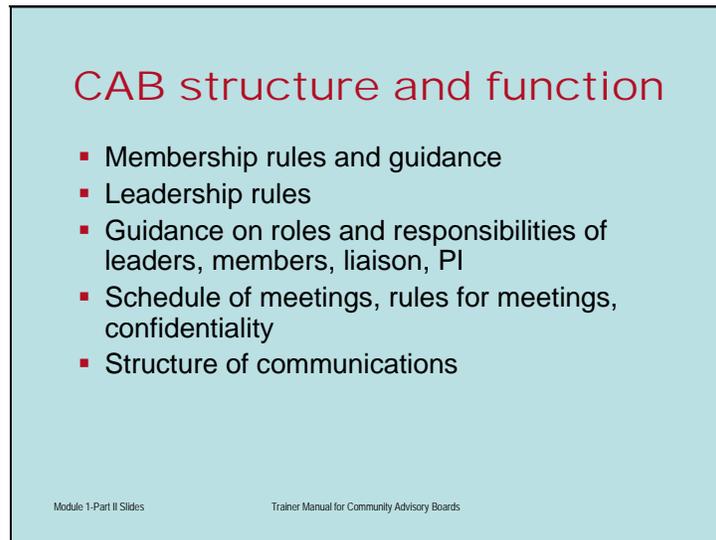
**Objective:** A result that can be measured  
*Example: “CAB members will attend the clinic on a monthly basis in order to discuss clinical research with families.”*

Module 1-Part II Slides Trainer Manual for Community Advisory Boards

- Next, the CAB may want to establish its goals and/or specific objectives. The **goal** of a CAB is its aim or purpose. An **objective** is a task to be completed or a result that can be measured, but these words are often used interchangeably.
- The goals and objectives of the CAB should support the mission statement and help define the role of the CAB.
- Writing and prioritizing the goals develops teamwork among within the CAB. These shared goals become the basis for the CAB’s objectives and plan of action. Creating specific objectives for each goal can help members feel they are making specific contributions to the community.
- It can be helpful if the stated objectives are measurable. For example, CAB members can keep track of how many families receive information about clinical trials each month.

**Trainer:** If appropriate for your setting, you may want to elicit other examples of possible goals and objectives for the CAB (related to the local CAB mission). The activity described in this module called the “SWOT analysis” is also helpful in helping CABs to identify and write goals and objectives.

## Slide 13



### CAB structure and function

- Membership rules and guidance
- Leadership rules
- Guidance on roles and responsibilities of leaders, members, liaison, PI
- Schedule of meetings, rules for meetings, confidentiality
- Structure of communications

Module 1-Part II Slides Trainer Manual for Community Advisory Boards

- It can be helpful (though not required) for the CAB to formalize its structure by agreeing on basic rules so the CAB functions smoothly. Sometimes these rules are called “standard operating procedures (or “SOPs). The number and types of rules CABs develop are different. There is no “right” or “wrong” way. Some examples of standard operating procedures are
  - A member’s name may be dropped from the active membership list after missing two (2) consecutive meetings of the CAB without prior notice to the meeting organizers.
  - A member’s name may be dropped from the active membership list and the mailing list when other CAB members agree that the member has made a breach of confidentiality.
  - The CAB will meet for a minimum of six (6) meetings per year, with additional meetings for special projects as needed
  
- Other examples of SOPs are provided in the appendices of the training manual.

## Slide 14

## Summary

- Researchers and their teams have a responsibility to work with and support a CAB.
- There are several helpful steps in the process of starting a local CAB,
  - providing training and mentorship
  - writing a mission statement
  - identifying goals
  - creating a structure and policies to guide the CAB.

Slide 15

## Group Activity: "SWOT" Analysis

- **S**trengths
- **W**eaknesses
- **O**pportunities
- **T**hreats



The illustration shows a woman in a white lab coat on the left, holding a microphone and a red balloon. To her right is a stick figure lifting a barbell. The background is light blue with yellow and red abstract shapes.

Module 1-Part II Slides      Trainer Manual for Community Advisory Boards

# SWOT ANALYSIS

## Module 1

### Time Frame (40 minutes)

#### Purpose

This small group exercise will give participants a chance to work as a team to think about the strengths and weakness they predict (or see) in starting and maintaining a CAB at their site. It is helpful for the participants to recognize and speak about their strengths, and to work together to overcome challenges they see or expect to see.

#### Materials needed

- Flipchart and marker for note taking (or a substitute such as a chalkboard if available)

#### Instructions

- Divide the participants into small groups of 4-6 members (The group can be smaller if there are few participants in the training. If there are fewer than 8 participants in the training, there may be only one group). In order to encourage new relationships, it's may be helpful to assign participants to a group rather than have the participants choose a group.
- Explain to the participants that you would like them to consider how their CAB (even if it is newly forming) will affect the research program at the site.
- Ask the groups to analyze the work of the CAB, and the impact the CAB may have, in these 4 categories, called a “**SWOT**” analysis:
  - **Strengths:** Examples might be that the CAB members are very enthusiastic and interested, that there are experienced CAB members at the site, that there are a large number of interested community members, or that there is good support from the principal investigator and/or the research team
  - **Weaknesses:** Examples might be a lack of interested community members or a lack of experience, or members having difficulty meeting the obligations of CAB membership. Another weakness could be a lack of standard operating procedures.\*  
\*You may want to show participants a set of Standard Operating Procedures (See Appendices).
  - **Opportunities:** Examples might be the chance to learn new skills, to collaborate with other CABs locally, regionally, or internationally, a chance to take on new responsibilities that will improve care or improve clinical trials participation.
  - **Threats:** Examples are disagreements among the CAB that make teamwork difficult, anticipated changes among the research team, or loss of an experienced CAB member, or fears of stigma by association with an HIV research group.
- Tell the groups to have one member record their lists for later reporting to the large group.
- Allow the groups 30 minutes for discussion and recording of their lists. Give the groups 5 minutes warning before time is up.

- Ask each group to report their lists to the large group, one at a time. Note the responses on the flip chart or chalkboard if available. If time is limited, or there are many groups, ask the reporters not to repeat comments that have already been reported by another group.
- Finish the exercise with a group discussion of how strengths and opportunities might be used to overcome weaknesses and threats. For example, with time and training an enthusiastic CAB might overcome the weakness of inexperience or lack of research knowledge. One way to start doing that is to ask and then answer these questions as a group:
  1. Are our goals and objectives realistic and is there a good chance they can be achieved? If the CAB has not yet identified goals and objectives, then this would be an opportunity to discuss how strengths and opportunities might be used by identifying possible broad goals that could be adapted to create a mission statement or goals and objectives for the CAB.
  2. How do we address our weaknesses or threats? How might they interfere with our goals or objectives?

## PARTICIPANT EVALUATION FORM

### Module 1 Part I

### Community Participation in Research

#### INSTRUCTIONS:

- Your opinion is important to us.
- There are no RIGHT or WRONG answers.
- Your answers are private. You do not need to put your name on this form.
- Please answer ALL the questions to help us improve this training.

**For questions 1 - 6, please rate the effect the training has had on your understanding of the following:**

0= No effect, 1= Some effect, 2= Much effect	No Effect	Some Effect	Much Effect
1. What a Community Advisory Board (CAB) is	0	1	2
2. The definitions of “IMPAACT” and “clinical trials network”	0	1	2
3. The different roles of the CAB	0	1	2
4. The difference between a CAB and a support group	0	1	2
5. The different levels of community participation (local, regional, etc.) within IMPAACT	0	1	2
6. The history of community participation in research	0	1	2

## PARTICIPANT EVALUATION FORM

### Module 1 Part II

### Community Participation in Research

#### INSTRUCTIONS:

- Your opinion is important to us.
- There are no RIGHT or WRONG answers.
- Your answers are private. You do not need to put your name on this form.
- Please answer ALL the questions to help us improve this training.

**For questions 1 - 6, please rate the effect the training has had on your understanding of the following:**

0= No effect, 1= Some effect, 2= Much effect	No Effect	Some Effect	Much Effect
1. Who should be a CAB member	0	1	2
2. How CAB members are prepared for their roles	0	1	2
3. Mission statements, goals, and objectives	0	1	2
4. The role of the Principal Investigator	0	1	2
5. The role of the CAB liaison	0	1	2
6. Strengths and weaknesses of our local CAB	0	1	2

*Please continue on the next page.*

*Please answer the following questions to the best of your ability:*

After this training, what help might you need to apply this information?

---

---

---

---

What part of this training did you find the **most useful**?

---

---

---

---

What changes would you suggest to make the training more useful?

---

---

---

---

What other training programs do you feel are important for you as a CAB member?

---

---

---

---

Other comments:

---

---

---

---

***Thank you for your comments!***

# TRAINERS' ASSESSMENT: POST-TRAINING

## Module 1

### Community Participation in Research

*Please document and evaluate the training for this module by estimating the level of improvement you observed in the participants' knowledge of Community Participation in Research. Making your notes while the training is still "fresh" in your mind will help you in planning for future training. Documentation of training will help your site show that the CAB is active and functioning.*

	NO IMPROVEMENT	SOME IMPROVEMENT	MAJOR IMPROVEMENT
1. Description of a community board purpose	0	1	2
2. Possible roles for CAB members	0	1	2
3. Overview of the IMPAACT network and how community representation is included at different levels	0	1	2
3. Roles of the principal investigator and CAB liaison	0	1	2

What changes would you suggest to make the training more useful?

---



---



---

What part of this training did you find the **most useful**?

---



---



---

Is there any part of this training that needs reinforcement?

---



---



---

Trainer Name:	Signature:	Date:
---------------	------------	-------

**Please use the back of this form for additional comments and suggestions.**





# **Module 1**

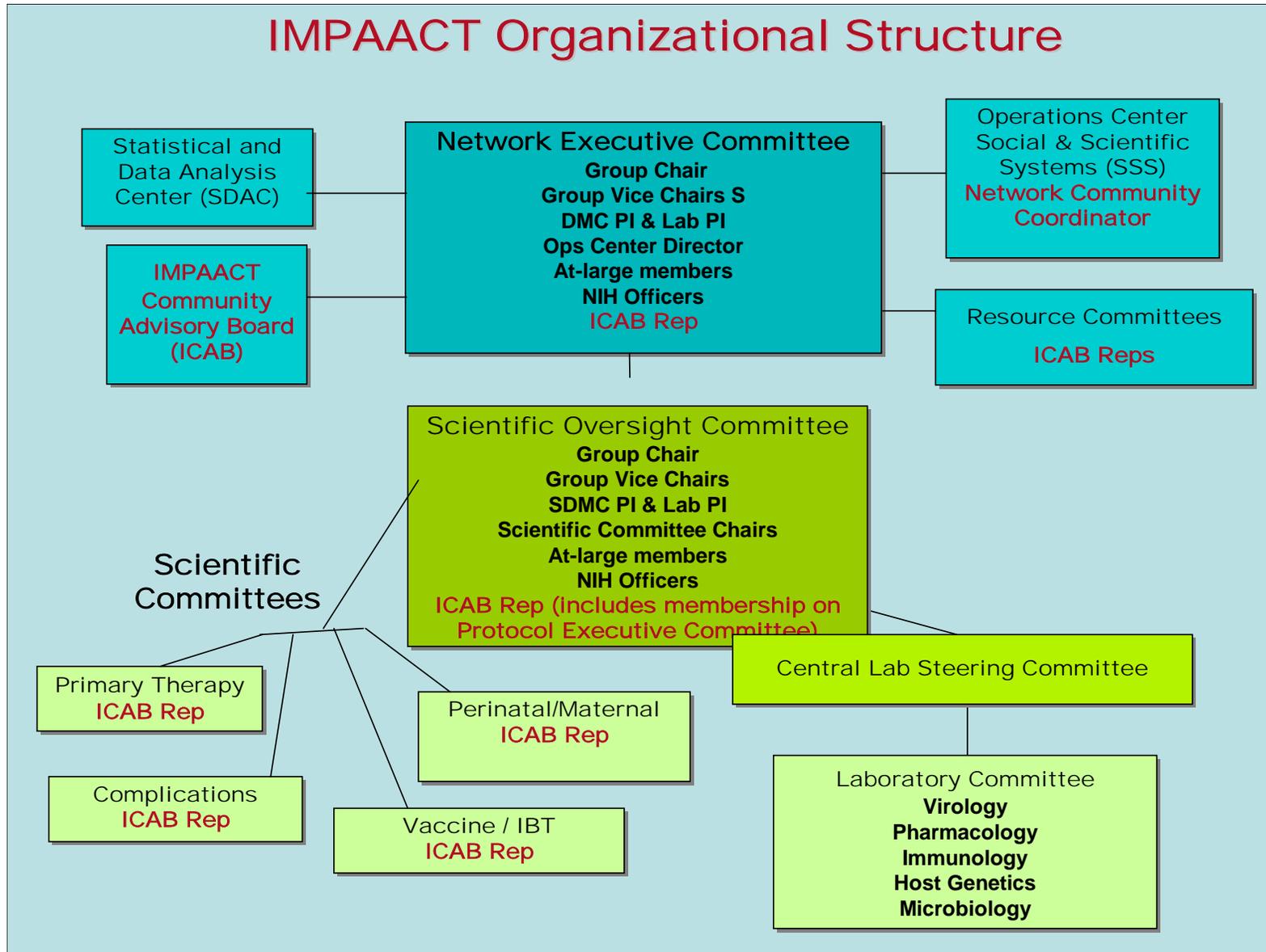
## **Appendices**





## APPENDIX 1

# IMPAACT Organizational Structure



## APPENDIX 2

### INTERNATIONAL MATERNAL, PEDIATRIC, ADOLESCENT AIDS CLINICAL TRIALS

#### Community Advisory Board Development Guidelines

The members of the Community Advisory Board that serves all of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Group's research sites (ICAB) believes that community involvement is vital to the research process, from developing the protocol, to doing the research, to sharing the results with the community.

The following are suggestions for community members and research teams to consider as they establish and maintain their CABs. As you go through the process of recruiting members for your CAB and developing a way to work together, it is important to remember that every CAB is unique in how it functions; each will reflect the culture of the community it serves. The major element that all CABs share is their role as a liaison between the community and the research team. To perform that role, it will be useful for each CAB to establish a basic foundation that will enable its members to work together effectively.

These guidelines suggest ways to build that foundation by covering the following topics:

- Developing a mission statement
- Identifying the CAB purpose and goals
- Determining the CAB's structure and function
  - By-laws or Standard Operating Procedures (SOPs)
  - Membership
    - Job description
    - Orientation and training
  - Leadership
  - Communication with researcher team
  - Role of the CAB liaison
  - Role of the principal investigator
  - Frequency of meetings
  - Meeting agendas

#### ***Developing a mission statement***

You will have the basic components of a mission statement when you write the answers to the following questions:

- Whom does the CAB serve?
- What does the CAB do?
- How does the CAB accomplish its goals? (in general terms)

Here is an example of how another CAB answered these questions:

*Whom?* Children and adolescents and their families who are HIV-infected or affected

*What?* To represent the needs and interests of the community to the research team

*How?* Learn about how the research process will affect the daily lives of the children, adolescents, and families who come to the clinic, and suggest to the research team ways in which they can prevent participating in the research from being troublesome.

Here is an example of the mission statement of a local CAB:

- *The mission of the Community Advisory Board (CAB) is to integrate community into the clinical trials site in order to advance HIV/AIDS research to meet the needs of medical science and the needs of infected and affected children, adolescents and their families in this community*

### **Identify the CAB goals**

The goals of your CAB should support the mission statement and help define the role of the CAB. Writing and prioritizing the goals develops teamwork and builds commitment to the work of the CAB. These shared goals become the basis for a plan of action, which will outline the steps CAB members will take to reach their goals.

Here is a suggested list of tasks:

1. Provide training so that CAB members can understand the research process
2. Provide input to the PI and research staff about the concerns and issues related to specific protocols. This includes participating in outreach and education
3. Provide feedback about clinic services.
4. Provide input to clinic staff about services the families need to participate in research (e.g. transportation, child care, food),
5. Help clinic staff organize activities and services for families, such as holiday events, informational meetings, setting up a food pantry or an emergency fund.
6. Help interpret findings of research to the community.
7. Help with recruiting new CAB members.

### **Determining CAB structure**

In addition to developing a mission statement and defining the goals of the CAB, some CABs draft Standard Operating Procedures (SOPs) to provide more structure. SOPs (sometimes called by-laws) might address the topics such as those given as examples here:

#### **Membership**

Membership can include parents, caregivers, adolescents, clinic staff, and other community members who work for HIV service organizations or other community organizations, such as religious institutions, children and family services, or legal aid

#### **Job Description**

The job description should tell the person being asked to join the CAB about their roles: to communicate the interests and needs of the community to the research team, to represent a specific community group infected with or affected by HIV, and to contribute their knowledge and skills to the work of the CAB. Those who want to join the CAB should be respectful of different points of view and willing to work together towards common goals.

**Leadership**

Some CABs have a chair and others have co-Chairs who are elected by the CAB members to provide direction, run the meetings, and distribute the work.

**Communicating with research team**

A clinic staff person must serve as the official liaison between the clinic staff and CAB. It is also important that the PI and other research staff regularly attend the CAB meetings to learn about the community and to answer questions and address the concerns of the community and the CAB members about the research.

**Role of the CAB liaison**

- Provide support to CAB. Coordinate Communications. Coordinate meetings/activities. Provide relevant information and materials.
- Be a resource so CAB members can have available technical expertise.
- Coordinate orientation and ongoing training to assist CAB members maintain their level of expertise.
- Coordinate CAB recruitment activities.

**Role of the principal investigator**

- Make sure enough training is available to support the CAB members.
- Communicate often and effectively with CAB members.
  - Keep the CAB members informed about scientific developments in the clinical trials.
  - Provide input on operational issues.
  - Offer technical expertise.

**Frequency of meetings**

Some CABs meet on a quarterly basis and others on a monthly basis. Each CAB also decides the time and place to have the meetings.

**Meeting agendas**

The CAB chair (or co-chairs) is responsible for setting the meeting agenda with the clinic staff liaison. Agendas vary among sites and usually include the PI providing updated information on current and new studies and an update from the clinical staff liaison on other clinic activities. Other items that might be on an agenda include planning an event for families who attend the clinic, starting a newsletter, or inviting a speaker to present information on a topic such as legal issues or disclosure, that affect the family.

## APPENDIX 3

### SAMPLE:

#### Community Advisory Board Standard Operating Procedures

##### **NAME**

###### Section 1:

The name of this organization shall be the Pediatric Community Advisory Board (CAB).

###### Section 2:

This organization shall be an unincorporated advisory panel, which conducts its principal activities within the \_\_\_\_\_.

##### **MEMBERSHIP**

###### Section 1:

The membership shall consist of three (3) categories, representing the community as follows:

- A. Parents/Caregivers of HIV-infected infants, children and adolescents and patients;
- B. HIV Service Providers/Medical Caregiver; and
- C. Community Members (interested people, religious leaders, school teachers, etc.).

###### Section 2:

The role of members of the Community Advisory Board (CAB) is to:

- A. Make a commitment to its processes and its results;
- B. Participate in all decisions and problem solving; and
- C. Undertake special tasks, as requested by the CAB.

###### Section 3:

CAB members are asked to serve a minimum of one (1) year, subject to reappointment.

###### Section 4:

A member's name may be dropped from the active membership list after missing two (2) consecutive meetings of the CAB without prior notice to the Co-Chairs or meeting organizers. A member's name may also be dropped from the active membership list and the mailing list when other CAB members agree that that member has made a breach of confidentiality.

###### Section 5:

A member may be reinstated once to the CAB after attending two (2) consecutive meetings.

###### Section 6:

The membership shall designate a CAB member who is a parent or caregiver to apply for membership with the Pediatric Community Constituency Group (PCCG), a Resource Committee that advises the Pediatric AIDS Clinical Trials Group (PACTG), the Chicago PACTU's parent organization. In addition to attending national PACTG meetings, the CAB member shall participate in pertinent conference calls and shall provide reports and updates to members of the CAB as needed.

**MEETINGS****Section 1:**

The CAB shall convene for a minimum of four (4) meetings per year, and additionally for specially called meetings as needed.

**Section 2:**

Meeting times shall be determined at the prior meeting and shall be located at \_\_\_\_\_ and may be called at any time or upon the written request of any five (5) members.

**Section 3:**

The staff liaison responsibilities to the CAB shall be outlined in Article VI.

**GUIDELINES****Section 1:**

The suggested duties and tasks of the CAB membership shall include but not be limited to:

- A. Identify unmet Pediatric, Adolescent & Maternal HIV needs within \_\_\_\_\_ and the surrounding areas;
- B. Assess the effectiveness of \_\_\_\_\_ Hospital's Pediatric, Adolescent and Maternal HIV programs and consumer satisfaction;
- C. Provide input on community outreach strategies, especially those targeting women, adolescents and children;
- D. Review HIV prevention/education tools to be used in the community (i.e., brochures, videos, etc.);
- E. Discuss new pediatric, perinatal and adolescent PACTG research protocols, informed consent forms and consent addendums, and provide feedback to the Principal Investigator and Research Coordinator of the PACTU; and
- F. Provide a forum where persons receiving services at \_\_\_\_\_ Hospital can voice concerns.

**Section 2:**

Encourage active discussion and participation of the CAB in all phases of PACTG protocol development, implementation, accrual and outcomes.

**Section 3:**

Some meetings shall be educational in nature to develop an educated constituency. This process will address basic science, protocol development and evaluation, the PACTG structure, the PCCG and the local Institutional Review Board (IRB) process.

**Section 4:**

The CAB and \_\_\_\_\_ Hospital staff will design and efficiently implement outreach programs to bring people of all socioeconomic statuses into clinical trials and to increase the participation of women, adolescents, children, people of color and under-served populations.

## **Co-Chair Role**

### Section 1:

The Co-Chair roles are to:

- A. Develop an agenda for each meeting;
- B. Co-Chair each meeting of the CAB, dividing responsibilities between each other;
- C. Participate in briefings prior to each meeting and debriefings after each meeting;
- D. Manage and resolve CAB conflicts; and
- E. Assist in coordinating subcommittees' work and reports, as needed.
- F.

### Section 2:

Each CAB Co-Chair shall serve a one-year term, or serve until their successors are elected.

### Section 3:

The CAB Co-Chairs shall attend and preside over a minimum of four (4) meetings per year, plus specially called meetings, as needed.

### Section 4:

In addition to the Duties and Tasks outlined for CAB members, the Co-Chairs will perform or participate in the following duties:

- A. Decide how the Co-Chairs shall share their joint responsibilities;
- B. Seek input from the CAB in determining an agenda for each meeting;
- C. Assist \_\_\_\_\_ Hospital staff in coordinating CAB meetings;
- D. Review the minutes from each meeting and ensure that an accurate portrayal of the deliberations of the CAB are presented;
- E. Obtain input from members on issues between meetings;
- F. Ensure that the CAB accomplishes its objectives.
- G.

### Section 5:

Elections for a Co-Chair shall take place in the summer for a term beginning the following September. Special elections to fill a position that has been declared vacant by a Co-Chair may be called by the other Co-Chair or the \_\_\_\_\_ Hospital staff liaison.

### Section 6:

A Co-Chair may be removed from office under the provision of the bylaws contained in Article II, Section 4.

### Section 7:

The outgoing Co-Chair shall educate and mentor the newly elected Co-Chair.

## **CAB Liaison Responsibilities**

### Section 1:

Staff members, directed by a designated liaison with the CAB, from \_\_\_\_\_ Hospital's Section of Pediatric and Maternal HIV Infection are accountable for coordinating the CAB and ensuring that the CAB's objectives are met.

**Section 2:**

Hospital staff responsibilities shall include but not be limited to:

- A. Organize the CAB meetings in coordination with the Co-Chairs
- B. Record and transcribe the minutes at each CAB meeting;
- C. Refer to the Co-Chairs any input received from members on issues between meetings;
- D. Search for articles regarding topics of concern to members;
- E. Clarify issues discussed at meetings if questions arise;
- F. Keep records of all member attendance;
- G. Organize mailings;
- H. Arrange meeting accommodations for members who have disabilities, dietary restrictions, transportation problems or other special needs; and
- I. Post notice of upcoming meetings in the clinic waiting areas so that persons receiving services at the CMH Special I.D. clinic may attend these meetings to voice concerns.
- J. Support special events and projects as designated by the Co-Chairs

**Decision-making:****Section 1:**

Decisions of the CAB shall be reached by consensus.

**Amendments to by-laws****Section 1:**

These bylaws may be amended at any meeting of the CAB, provided that notice of the proposed change(s) shall have been given either by mail to each CAB member at least fourteen (14) days prior to the date of such meeting, or by verbal announcement at the preceding meeting.

SAMPLE continued:  
Southeast AIDS Pediatric Clinical Trails Unit (SEPACTU)

1. Membership

- Meetings are open to anyone who is interested in HIV/AIDS research, especially research involving children, adolescents and mothers. Persons attending a meeting may add their name and contact information to our membership list.
- The membership list is reviewed periodically. Persons who have made no contact or have attended no meetings in a twelve-month period may be dropped from the membership list.

2. Meetings

- Regular meetings are held only four times each year.
- Meetings are held on Mondays at mid-day in a conference room at the hospital. Lunch is served at 11:30, business begins by 12:00. Meetings usually end by 1:00.
- Additional meetings on special topics may be called with the approval of the membership.
- In addition, communication via email and telephone can be arranged should the need arise.
- Programs usually include a speaker on a specific research topic. Current and upcoming AIDS research at SEPACTU is discussed.
- The dates of the meetings do not follow an exact schedule. At each meeting, a determination of the date of the next meeting is made with an effort to avoid holidays, conferences, and other schedule conflicts of members, principal investigators, and staff of the SEPACTU.

3. Leadership

- The only "officer" is the CAB chair, who whenever possible will be the parent or guardian of a child or adolescent living with HIV/AIDS.
- The chair is selected by agreement of the CAB membership.
- Others pitch in to help with setting up the meeting, cleaning up afterwards, taking attendance, taking minutes, leading discussions, etc.
- The structure is very loose, and anyone is welcome to volunteer to help.

4. Attendance at national meetings

- The CAB chair will represent the CAB at national PACTG meetings except when he/she is unavailable, or is going to the meeting in another capacity (such as CCG representative) then the opportunity to represent the CAB at the national meeting will be rotated among interested CAB members, selected by agreement of the CAB membership and site staff.
- Expenses
- Some members travel from out of town to attend our CAB meetings. If there are other sources of funds to cover their travel expenses, we ask they be pursued first. But when there are no other funds available, the SEPACTU will reimburse members for reasonable travel expenses. Forms to apply for reimbursement are available at each meeting.