

THE ROLE OF COMMUNITY ADVISORY BOARDS (CABs) IN CLINICAL TRIALS



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INTRODUCTION

- UNAIDS/WHO, 2007 Guidance Document states that researchers and trial sponsors should consult communities through a transparent participatory process
- CABs purpose is therefore to ensure active community participation during HIV vaccine trials

BACKGROUND OF THE CABs

- Started in the (USA) and Europe in the 1980's and later established in Nyanga, Cape Town in 2004
- Established with the intention of ensuring that trials are run ethically
- Established so communities can benefit by gaining access to information about HIV vaccines and other prevention methods

CAB INVOLVEMENT AND PARTICIPATION

- Members of a particular community participate in CAB on a voluntary basis
- CAB membership should be as diverse and representative as possible of the local population that they represent
- As a consequence, this will also create diversity of educational backgrounds and expertise

RECOMMENDATIONS

- In February 2009 the National Institute of Allergy and Infectious Diseases compiled a document with Recommendations for Community Involvement in HIV/AIDS Clinical Trials Research
- These recommendations will be reflected in this presentation...

LAYING THE FOUNDATION

Roles	Responsibilities of Site CAB
Gather Information for Community Profile	<ul style="list-style-type: none"><li data-bbox="636 496 1944 816">• Help researchers and research staff to better understand the community (e.g., characteristics and organization)<li data-bbox="636 959 1682 1024">• Identify key community leaders<li data-bbox="636 1182 1780 1354">• Build partnerships with community-based organizations

...LAYING THE FOUNDATION

Roles	Responsibilities of Site CAB
Educate and Train	<ul style="list-style-type: none"><li data-bbox="556 422 1953 714">• Educate research staff about the needs of the community and best ways to reach specific segments of the population<li data-bbox="556 844 1953 1169">• Provide the research staff with simple, culturally appropriate terms for complex scientific language<li data-bbox="556 1299 1953 1477">• Educate researchers about community concerns and research priorities

...LAYING THE FOUNDATION

Roles	Responsibilities of Site CAB
CAB Development and Recruitment	<ul style="list-style-type: none">• Work with researchers and research staff to clarify the mission as well as roles and responsibilities of the CAB • Coordinate organization and governance of the CAB by addressing:<ul style="list-style-type: none">o frequency and facilitation of meetingso agenda developmento engagement of broader community (non CAB members)

...LAYING THE FOUNDATION

Roles	Responsibilities of Site CAB
CAB Development and Recruitment	<ul style="list-style-type: none"><li data-bbox="682 500 1829 789">• Identify training needs of CAB members and help organize and facilitate these trainings<li data-bbox="682 948 1808 1008">• Identify criteria for self-evaluation<li data-bbox="682 1170 1724 1338">• Discuss evaluation criteria with researchers and research staff

COMMUNITY PREPAREDNESS

Roles	Responsibilities of Site CAB
<p data-bbox="58 423 317 480">Consult:</p> <p data-bbox="58 646 617 894">Communication Streams between staff and CABs need to be open and transparent</p>	<p data-bbox="667 440 2028 724">Introduce the researchers and the community to one another. Discussions may include:</p> <ul data-bbox="674 800 2022 1471" style="list-style-type: none"><li data-bbox="674 800 1955 862">• Overview of the organization/network<li data-bbox="674 1003 1898 1065">• General information about research<li data-bbox="674 1206 2022 1268">• Research experiences in the community<li data-bbox="674 1409 1646 1471">• Perceived research benefits

...COMMUNITY PREPAREDNESS

Roles	Responsibilities of Site CAB
<p data-bbox="58 435 319 493">Consult:</p> <p data-bbox="58 623 617 1068">Communication Streams between staff and CABs need to be open and transparent</p>	<ul data-bbox="684 467 1915 1481" style="list-style-type: none"><li data-bbox="684 467 1915 750">• Community perspective on need for HIV research areas of research needed, etc.<li data-bbox="684 899 1852 958">• Overview of the research question<li data-bbox="684 1107 1839 1166">• Introduction of new research plan<li data-bbox="684 1315 1839 1481">• Difference between research and clinical care

...COMMUNITY PREPAREDNESS

Roles	Responsibilities of Site CAB
<p data-bbox="58 461 401 529">Strategize:</p> <p data-bbox="58 667 621 1393">Formulate a community involvement plan that serves to capture how the site will engage the community and the CAB</p>	<ul data-bbox="726 480 1990 1219" style="list-style-type: none"><li data-bbox="726 480 1877 769">• Identify and meet with community members and community-based organizations<li data-bbox="726 927 1990 1219">• Conduct awareness campaigns and propose innovative ways to reach out to the community

...COMMUNITY PREPAREDNESS

Roles	Responsibilities of Site CAB
Prepare	<p>Educate the community about:</p> <ul style="list-style-type: none">• Importance of research to the public health• Clinical trials research• Specific objectives of this research• Possible impact, risks and benefits of proposed research• Role of a CAB

...COMMUNITY PREPAREDNESS

Roles	Responsibilities of Network CAB
Inform	<ul style="list-style-type: none">• Train site CABs in community preparedness strategy: what it is, how to do it, why it is important
Share Information	<ul style="list-style-type: none">• Help sites share best practices, challenges, and successes they have experienced
Advocate	<ul style="list-style-type: none">• Ensure that community preparedness activities are defined in the CTU's development plans and that they are budgeted for
Evaluate	<ul style="list-style-type: none">• Participate in evaluating site and network CABs and community engagement activities

DEVELOPING THE RESEARCH PROTOCOL

Roles	Responsibilities of Site CAB
CONCEPT PHASE	
Community and Public Health Considerations	<ul style="list-style-type: none">• Contribute public health and community information generated from interactions between the CAB and potential trial participants that will help researchers shape the research concept
Research Question Considerations	<ul style="list-style-type: none">• Help determine the importance of the research being proposed to the community

...DEVELOPING THE RESEARCH PROTOCOL

Roles	Responsibilities of Site CAB
PROTOCOL DEVELOPMENT PHASE	
Context for Research Question	<ul style="list-style-type: none">• Learn what is known about the research question
Study Design	<ul style="list-style-type: none">• Contribute community-relevant information that would help with designing a research protocol that can be implemented within a proposed timeframe

...DEVELOPING THE RESEARCH PROTOCOL

Roles

Responsibilities of Site CAB

PROTOCOL REGULATORY PROCESS AND PREPARATION FOR IMPLEMENTATION

Consents

- Understand the reason for the informed consent document and the implication of signing it
- Ensure that the informed consent document is understandable and in lay language
- Ensure that the informed consent clearly states that consent to participate in a study may be withdrawn anytime
- Help the community understand all aspects of informed consent

...DEVELOPING THE RESEARCH PROTOCOL

Roles	Responsibilities of Network CAB
Material Education	<ul style="list-style-type: none">• Contribute to educational material by identifying gaps in existing material and suggesting needed topics for community education
Participate on Scientific Committees	<ul style="list-style-type: none">• Bring community perspective to all discussions; bring information to network CAB about scientific committee considerations
Participate on Protocol Teams	<ul style="list-style-type: none">• Help protocol team consider participant issues when defining criteria for inclusion, exclusion, schedule of evaluations, etc.

IMPLEMENTING THE RESEARCH STUDY

Roles	Responsibilities of Site CAB
Inform	<p>Become informed about the research study including:</p> <ul style="list-style-type: none">• the reason the study is being done,• the products being tested,• the study design, and• the implementation plan

...IMPLEMENTING THE RESEARCH STUDY

Roles	Responsibilities of Site CAB
Educate	<ul style="list-style-type: none"><li data-bbox="436 396 1797 565">• Share information with and educate the community about the value of the research<li data-bbox="436 667 1969 948">• Develop a tool (such as a suggestion box) to give researchers monthly feedback concerning the study 's impact on the community<li data-bbox="436 1050 1934 1219">• Advise researchers and research staff on how to improve outreach to the local target population<li data-bbox="436 1321 1934 1490">• Identify and facilitate communication pathways with the local site target population (s)

...IMPLEMENTING THE RESEARCH STUDY

Roles	Responsibilities of Site CAB
Educate	<ul style="list-style-type: none"><li data-bbox="464 483 1976 662">• Learn about myths and misconceptions about the trial and report back to the research staff<li data-bbox="464 818 2032 997">• Learn about Data and Safety Monitoring Boards (DSMB)<li data-bbox="464 1153 1625 1442">• Educate the community about the role/importance of IRBs and DSMB Recommendations

...IMPLEMENTING THE RESEARCH STUDY

Roles	Responsibilities of Site CAB
Advocate	<ul style="list-style-type: none">• Ensure that concerns are addressed appropriately, including any issues with the informed consent process
Oversight	<ul style="list-style-type: none">• Stay abreast of study progress, enrollment, and interim reports from the DSMB
Roles	Responsibilities of Network CAB
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COMMUNICATING RESEARCH RESULTS

Roles	Responsibilities of Site CAB
Gather Information	<ul style="list-style-type: none">• Participate in research updates; learn about the potential impact of study results
Information Sharing	<ul style="list-style-type: none">• Provide feedback to the broader community about:<ul style="list-style-type: none">○ why the study was conducted○ findings of the study○ key messages○ impact on clinical care and/or prevention strategies and future research• Work with CTU/CRS, as appropriate, to share information via newsletters, radio, or other media outlets

...COMMUNICATING RESEARCH RESULTS

Roles	Responsibilities of Site CAB
Consult	<ul style="list-style-type: none"><li data-bbox="468 467 1923 873">• Consult key stakeholders on specific target audiences to reach with results, how best to link with local target populations, and how relay information about the trial results<li data-bbox="468 1032 1990 1318">• Ensure communication materials are written in clear, understandable lay language and/or are translated as needed

...COMMUNICATING RESEARCH RESULTS

Roles	Responsibilities of Network CAB
Advocate	<ul style="list-style-type: none">• Ensure that CAB members understand the study results so that they can advocate for additional research or policy changes
Inform Other Networks	<ul style="list-style-type: none">• Inform/educate Community Partners about research findings
Share Information	<ul style="list-style-type: none">• Work with community educators and/or network staff to review communication materials to ensure appropriateness for target population (s)• Work with network staff to identify/develop mechanisms for sharing information such as forums, workshops, etc.

CONCLUSION

- Great strides have been made in developing a workable community engagement model such as the CAB model
- This model demonstrates that only through effective partnerships can clinical trials be conducted in a transparent and ethical manner

QUESTIONS ??

THANK YOU !!