Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research

Rona Siskind, Division of AIDS

HIV Prevention Trials Network Community Working Group
June 9, 2011
Recommendations
Document Overview

Goal:

- To help define, harmonize and improve the role of community in the research process
- To assist research staff as they seek community input and engagement
- Foster a stronger partnership between the research staff and the community
Community Advisory Boards (CABs)

- Generally consist of community members who represent those who have a stake in the research
- Members may include:
  - Trial participants
  - Patient advocacy groups
  - Health care workers
  - Family members or friends
  - Non-governmental organizations
  - Local government officials
CAB Responsibilities

- Help the broader community understand research goals and relay information
- Provide information about communities’ needs and concerns to researchers
- Facilitate researchers’ understanding of community
- Participate in protocol development process
  - Review all research related documents/materials
CAB Responsibilities

- Provide linkages to targeted communities & assistance in developing partnerships
- Review translated documents
- Advise on disseminating information about planned and ongoing research activities and research results
  - Review materials to ensure clarity and translation
Document Framework

- Roles and Responsibilities
- Management and Support Needs
- Laying the Foundation
- Community Preparedness
- Developing the Research Protocol
- Implementing the Study
- Communicating Research Results
Laying the Foundation

- Researchers gather information and develop community profile
- Information about community will inform research staff about community needs/concerns/priorities
- Researchers inform community about:
  - Research goals and potential benefits
  - Opportunities for involvement
- Researchers begin process to establish CAB
- In partnership with CABs, develop clear mission and defined roles and responsibilities
- Sustain community structure for ongoing input
Community Preparedness

- Establish open streams of communication between staff and CAB
- Research staff formulate a community involvement plan – delineate how site will engage the CAB and broader community
- Research staff educate the community about clinical trials research and potential impact/objective of specific trial(s) being considered
Developing the Research Protocol

- Learn about the proposed research & determine importance to the community
- Help researchers shape research concept & study design
- Advise on informed consent process and review all documents
- Review/contribute to educational materials
- Stay apprised of study progress, enrollment, and interim reports
- Participate on scientific committees and protocol teams (network level CAB)
Implementing the Research Study

• Be informed about the research study and continue to provide feedback on the study’s impact on the community (e.g., interest, concerns)
• Stay abreast of study progress (e.g., enrollment, DSMB interim reports)
Communicating Research Results

- Learn about potential impact of study results
- Provide feedback to community
  - Why study was conducted
  - Findings
  - Key messages
  - Impact on care, prevention and/or future research
- Provide input on how research results should be communicated and how to reach target populations
- Review materials for clarity, lay language, and accuracy of translations
Summary

- Community awareness, understanding & support of research is critical to trial success
- CAB model is one form of community engagement
- Unique aspects/needs of a community, research site or network should be considered as plans for community engagement evolve
Where to Find the Recommendations Document

On the HANC Web Site
http://www.hanc.info/cp/resources/Pages/recommendationsInvolvement.aspx

On the NIAID Web Site
http://www.niaid.nih.gov/ABOUT/ORGANIZATION/DAIDS/NETWORKS/Pages/daidsnetcoord.aspx