



Study Site HPTN XXX Standard Operating Procedure (SOP)

SOP No.: HPTN XXX XX

Title: Sample SOP for Community Involvement

Effective Date: Day Month Year

Purpose:

This SOP describes procedures for engagement of community stakeholders, community involvement, and development and support of the Community Advisory Board (CAB) in the implementation of the HPTN XXX study protocol. This SOP standardizes the process by which community involvement activities will be undertaken by the clinical research site (CRS).

Scope:

These procedures will apply to all HPTN XXX study staff and CAB members involved in the HPTN XXX research study, and community stakeholders who are working in the research community with potential study participants throughout the study period.

References:

1. HPTN Manual of Operations & Operating Policies, Section 5: Community Participation in the HPTN, Date of Issue: March 2007 (<http://www.hptn.org/HPTNMOP2007/HPTNMOP2007.htm>)
2. HPTN Community Involvement Work Plan (CIWP)
3. HPTN Community Program (http://www.hptn.org/community_program.htm)

Definitions:

1. ASO – AIDS Service Organizations
2. CAB – Community Advisory Board
3. CE – Community Educator
4. CIWP – Community Involvement Work Plan
5. CORE – Coordinating and Operations Center
6. CRS – Clinical Research Site
7. CWG – Community Working Group
8. FHI – Family Health International
9. HPTN – HIV Prevention Trials Network
10. IoR – Investigator of Record
11. NGO – Non-Governmental Organizations
12. PI – Principal Investigator
13. PLHA – People living with HIV/AIDS
14. SOP – Standard Operating Procedure

Responsibilities:

1. Site Principal Investigator (PI) is ultimately responsible for ensuring that the following procedures are carried out according to this SOP in a timely manner.
2. Site PI is responsible for ensuring that the CAB is well represented and elicits community involvement at all levels in the design, development, implementation, and dissemination of results for the study.
3. CAB Chairperson is responsible for the organization of all CAB meetings and the regular reporting of CAB progress to the Site PI.
4. All CAB members are responsible for the dissemination of information about research projects to their perspective community.
5. The Community Educator (CE) is responsible for working with other research staff and community stakeholders to develop and maintain the site's relationship with the community, acting as the facilitator of community involvement activities.
6. The Community Working Group (CWG) representatives are responsible for enhancing study specific community strategies and/or identify possible challenges by
 - a. Ensuring the development of CIWP prior to study activation and the submission to FHI CORE Community Program staff.
 - b. Ensuring that recruitment and retention plans are developed in conjunction with the site CE, outreach teams and CAB members.
 - c. Informing clinical research staff of potential social harms which may emerge prior to study activation or during implementation and ensure that these social harms are addressed as part of the sites CIWP.
 - d. Assisting in the development of study specific educational tool kits and communication plans for information dissemination.
 - e. Keeping community members informed of executive committee and community

Community Advisory Board's Objectives:

1. To strengthen the relationship and communication between the general community and study researchers
2. To evaluate the impact of HPTN studies on local communities
3. To involve the community in the design research methodology and conduct of the study that would best serve the study participants
4. To serve as a voice for the community and study participants
5. To protect the welfare of the community and participants throughout the research study

Procedures:

1. In collaboration with the HPTN study staff, an annual Community Involvement Work Plan (CIWP) will be created to assess the community's needs, and to identify clear goals in the planning, implementation, and evaluation of the study. (Please refer to HPTN CIWP for details)

- 1.1. Assess the community where the research will be conducted to identify the following
 - 1.1.1. Community-related challenges for the site related to the study.
 - 1.1.2. Changes in the population that could impact the education, awareness and sensitization efforts.
 - 1.1.3. Events occurring in the community that could adversely affect
 - 1.1.3.1. study accrual
 - 1.1.3.2. retention and adherence
 - 1.1.3.3. community ownership of the study
 - 1.1.4. New messages or information regarding upcoming trials that need to be considered when planning community education, awareness and sensitization efforts.
- 1.2. Identify and develop a course of action to be conducted by site staff and community advisors to ensure a collaborative community participation process
 - 1.2.1. Community Education Staff and CAB members will identify community based organizations (CBO), non-governmental organizations (NGO), AIDS service organizations (ASO) and other community stakeholders who provide direct and/or indirect services to the targeted communities.
 - 1.2.2. One-on-one or group meetings will be arranged with the community leaders and organizations identified.
 - 1.2.3. These meetings will provide community organizations and stakeholders a general understand the following:
 - 1.2.3.1. Overview of the research study
 - 1.2.3.2. Benefits of research for study participants
 - 1.2.3.3. Overview of the HPTNs community involvement program
 - 1.2.3.4. Available support systems for potential study participants
 - 1.2.3.5. Study referral process
 - 1.2.4. Partnerships will be formed with interested organizations to aid with (but not limited to) the following:
 - 1.2.4.1. Study referral
 - 1.2.4.2. Community outreach
 - 1.2.4.3. Recruitment and retention

- 1.2.5. Community Education Staff will identify community education needs and develop appropriate educational strategies to increase community understanding of (but not limited) to the following topics
 - 1.2.5.1. HIV/AIDS
 - 1.2.5.2. HIV Prevention Strategies
 - 1.2.5.3. HPTN XXX Overview
 - 1.2.5.4. Clinical Research
 - 1.2.5.5. Community Involvement
 - 1.2.6. Community Education Staff and CAB members will identify potential educational sites.
 - 1.2.7. Group educational sessions about the study and other health issues that affect the community will be facilitated by CRS staff.
 - 1.3. Implementation: Preparing an implementation schedule that lays out the sequence, timeline, and individual responsibilities for project activities
 - 1.4. The Investigator of Record (IoR) and CAB Chair (or designee) must sign off on the work plan prior to submission to the FHI Coordinating and Operations Center (CORE), as documentation that they were each involved in its preparation and concur with its contents.
 - 1.5. The CE will be responsible in submitting the annual CIWP in a timely manner. S/he is also responsible for submitting monthly reports to the FHI CORE on the community objectives outlined in the work plan.
2. Development of Community Advisory Board (CAB)
 - 2.1. CAB will be established and its members selected before the initiation of the study.
 - 2.2. To ensure CAB autonomy and to reduce the potential for conflict of interest, CAB members are volunteers from the local community.
 - 2.3. All study research staff are restricted from becoming a CAB member.
 - 2.4. Representatives of various facets, including but not limited to the following:
 - 2.4.1. Non-Governmental Organizations (NGOs)
 - 2.4.2. AIDS Service Organizations (ASOs)
 - 2.4.3. People living with HIV/AIDS (PLHA)
 - 2.4.4. Government Agencies
 - 2.4.5. Professionals
 - 2.4.6. Black Men and Women
 - 2.4.7. Hispanic Men and Women

- 2.4.8. Other interested community members as deemed appropriate
- 2.5. Interested individuals will be invited to the initial establishment meeting/orientation to:
 - 2.5.1. Introduce XXX study objectives, plans, and goals.
 - 2.5.2. Introduce Community Outreach Workers and Educator(s)
 - 2.5.3. Discuss the functions and responsibilities of CAB
 - 2.5.4. Develop plans to recruit new members and involve community to ensure that CAB will be well represented
- 2.6. The terms of membership and responsibilities of all CAB members include the following:
 - 2.6.1. Attend CAB meetings
 - 2.6.2. Provide feedback on issues under discussion
 - 2.6.3. Voice concerns from the communities and study participants
 - 2.6.4. Disseminate study information to local community
 - 2.6.5. Collaborate with the CE in the development and implementation of the site's community participation activities
 - 2.6.6. Recruit and orient new CAB members
 - 2.6.7. Advise the study site on necessary budget items needed to support community participation in the local HIV prevention research efforts
- 2.7. While membership is open to all members of the community who successfully complete the initial CAB meeting/orientation, the total active membership should not exceed 20. If interested individuals exceed 20, the following will take place:
 - 2.7.1. In order to have representation from all facets of the community, each individual interested in becoming a member will be divided into categories of representative listed in section 1.4 of this document. Any category with more than 3 potential representatives will then be enlisted in a random name drawing.
 - 2.7.1.1. Separate name drawings will be conducted within each category in which two representatives from each category will be selected in the first round.

- 2.7.1.2. If active membership is still available after the first round of drawing, the names of all individuals who were not selected in the first round will be pooled into one drawing and then be randomly selected into CAB until the number of members reaches 20.
- 2.7.1.3. The term of active membership will be limited to three years. Reselection of members will then be conducted in the same manner described above.
- 2.7.1.4. For those who were not selective as an active member, they can choose to become an inactive member, meaning they will not have the right to vote but can attend all CAB meetings for that year.
- 2.7.2. If the number of interested individuals does not exceed 20, then CAB membership will be automatically renewed for all active members.
- 2.7.3. Active membership is defined as a CAB member who has attended at least half of all regular CAB meetings within one year of his/her appointment.
- 2.7.4. A CAB member is considered non-active if s/he is absent from three consecutive regular CAB meetings and/or if s/he attended less than half of all regular CAB meetings within one year of his/her appointment.

3. CAB's Function and Involvement

- 3.1. Upon the selection of its members, individuals from CAB can then be nominated for the Chairperson position.
 - 3.1.1. One individual will then be selected as the chairperson through a member only voting process in which each member can cast one vote.
 - 3.1.2. The nominee with the highest number of votes will then be elected. S/he will be serving a 3 year term from the date of appointment.
 - 3.1.3. The elected Chairperson will be eligible to be nominated again for a consecutive second term, but will not be allowed to be nominated for the post thereafter.

4. Support of the CAB

- 4.1. To ensure active participation from community representatives for research design and implementation, CAB meetings are required at least three months prior to the initiation of the study and throughout the research study process.
 - 4.2. The CAB Chairperson and/or CE will be responsible for contacting the members for the regular meeting time as well as disseminating the meeting information to the research site.
 - 4.3. Participation in the regular CAB meeting by the research study staff, especially the CE, is encouraged, though not required.
 - 4.4. Transportation reimbursement will be offered to all CAB members at the conclusion of each CAB meeting.
5. Documentation of CAB meeting
- 5.1. The CAB Chairperson, or a designee, will be responsible for the recording the minutes for each meeting.
 - 5.2. All attendees are required to sign in the attendance log for each meeting. (Appendix I)
 - 5.3. All documentation should be maintained at the CAB administrative office.

History

Version	Review Date	Effective Date	Change
xxx-xx	Day Month Year	Day Month Year	

Approval

Author, Author's Title

Date:

Approval's Name, Approver's Title

Date:

Appendix I: CAB Attendance Log



Community Advisory Board (CAB) Attendance Log

Date, Time and Location			
Name	Affiliation	Telephone	Signature

CAB Chairperson's Signature: _____

Date: _____