



HIV VACCINE
TRIALS NETWORK

HVTN Standard Operating Procedures

Community Education/Community Participation

Guidelines for Best Practices

Operating Principle:

The HVTN Global Community Education Plan (Domestic & International) shall establish processes for arriving at standards and best practices at international, national, and local levels.

Through collaboration and consultation with the Core, each HVTU will:

- ensure the ethical and scientific quality of proposed research,
- ensure relevance to the affected community,
- evaluate acceptance by the affected community
- support involvement of community representatives in the design, development, implementation, and distribution of results.

Community Advisory Boards and Non-Governmental Organization Constituency Groups will:

- assist in development of educational programs
- advise on study design in relation to volunteer concerns
- advise on readiness of cohorts to join large-scale trials
- inform SSC on Network issues
- build collaboration with other prevention efforts and educational campaigns

The HVTN is committed to:

- the right of each community advisory board to determine its own priorities, methods of organization, and programs, and to have these choices respected by the local organization
- the maximum involvement of women and men living with HIV/AIDS in all aspects of the network's research
- recognition that there are diverse social and cultural perspectives on HIV/AIDS, but these should not override fundamental human rights to respect individual dignity and protection against political, social, and religious intolerance
- non-discrimination in all areas regarding HIV status, gender, religion, race, sexual orientation, sex-work, drug use, cultural, or social status;

Diversity within the CAB can be inclusive but not limited to:

- members of different ethnic groups and persons with different risks for HIV,
- a cross-section of the populations included in the study (i.e., women, gay and bisexual men), individuals who represent health care, legal and service organizations and
- participants in the study.

COMMUNITY EDUCATION/COMMUNITY PARTICIPATION

1. Community Education/Relations

I. Policy:

Each HVTN research site will develop and implement a community education plan.

II. Rational:

An aware, knowledgeable, and engaged community throughout the research process and beyond is an imperative. Providing communities with the tools for engagement and a true partnership between researchers and the community, requires that communities have ongoing access to up-to-date culturally and linguistically appropriate information; facilitated opportunities for ongoing learning and participation; and ongoing interaction with site staff. Community education/relations should be encouraged to complement the research efforts conducted by the site.

Educational strategies should focus on increasing participation in and awareness of trial participants, members of communities infected and affected by HIV and the community at-large about HIV prevention vaccine research; scientific concerns in the design and development of clinical trials; and the overall efforts of the research network. At the same time, community education efforts should also include strategies that increase the knowledge level of researchers and staff about historical, cultural, social and political issues and needs of the community and facilitate ongoing reciprocal learning and interaction between community members and researchers. Overall, it should be noted that community education is not recruitment, but rather an ongoing process that helps to lay the foundation for recruitment and ongoing dialogue between community members and researchers.

III. Implementation:

The HVTN Core will work with sites to develop plans for community education (the overall goals, objectives and scope). The core will provide oversight and operational management to ensure the coordination and integration between materials development and dissemination; collaboration and partnership development; and the ongoing education of trial participants, researchers and the community at-large. A budget and human resources should be dedicated to assist in facilitating the ongoing development, implementation and coordination of community education initiatives at each HVTN site. A site-specific educational plan should be developed in partnership with community advisory board members and should be supported by a community assessment identifying community education needs, potential benefits and barriers, and appropriate educational strategies to be employed. This educational plan should be accompanied by a periodic monitoring and evaluation plan.

2. Community Advisory Boards

I. Policy:

Community members will be involved early in discussing prevention research priorities; research design issues such as cohort selection criteria, questionnaire design, and follow-up plans; informed consent procedures; risk-reduction interventions; community education and outreach; and recruitment and retention planning.

Sustained relationships and communication with community members will be the responsibility of each research site Principal Investigator. Staff will develop a written plan to foster trust; to ensure respect of social, cultural, and political realities of the communities where recruitment will take place; and to maximize opportunities for dialogue about the implementation of research trials. This involvement and participation of community members must be supported as an integral part of the site operating plan.

II. Rationale:

Clinical trials of HIV vaccines and other prevention interventions are most likely to succeed when all the parties concerned - researchers, government, manufacturers, and community - regard the trials as a collaborative process. Community members, particularly potential trial volunteers and people from the populations from which volunteers will be recruited, can and should play an integral role in advising on research trials.

III. Implementation:

Community Advisory Boards will be developed at all HVTN sites.

The HVTN Core will establish a Global CAB that will meet on a regular basis (preferably monthly.) Members from each research site will participate in conference calls and be ensured representation at an annual retreat. This Global CAB should minimally convene quarterly to review international issues and facilitate information exchange.

The HVTN Core will outline steps to develop, maintain, support, and encourage the full participation of community representatives in all phases of the research process. This will include plans for recruitment, ongoing orientation, training and education, and facilitated access to participation on science direction working groups and network governance.

HIV Vaccine Trial Unit (HVTU) CABs

These are common elements of the local CABs mission and operating statements:

- to provide to investigators informed commentary regarding: study protocols including documents related to the informed consent process, informational and educational materials, and recruitment.
- to collect and make available to study staff and to HVTN information that can be used to address concerns likely to arise during trials.
- to support judicious recruitment efforts and promote referral arrangements for participants in prevention intervention trials.
- to address issues of discrimination that are related to this type of research study (i.e., testing HIV-positive);
- to address issues of HIV testing aversion, particularly within minority populations.
- voicing community concerns or issues related to the proposed study,
- to provide recommendations regarding planning and review of the study objectives and implementation.

3. Protection of Research Subjects

I. Policy:

At all levels including design, informed consent process, and the implementation of study protocols, efforts will be made to ensure that every precaution is taken to minimize potential harms to trial volunteers.

II. Rationale:

The primary concern of any HVTN clinical study is to ensure answers to the research questions being asked, with the greatest possible efficiency of design and the maximal benefit, respect, and justice for the populations where the research is being conducted. In this regard, protection of research participants is a major concern, and involves protection against physical, social and ethical harms including:

- physical disturbances, disability, or death suffered by the participant as a result of trial participation;
- discrimination or other social effects such as fractured family and personal relationships, job discrimination, inability to travel in some foreign countries, loss of insurance and potential discrimination if incarcerated;
- ethical breeches such as incomplete or unequal access to information or care;
- enrollment in research that is unnecessarily risky;
- enrollment in research that carries no benefit to the populations where the study is being conducted;
- enrollment in research without a complete informed or autonomous consent process;
- enrollment in research that is so poorly designed as to be a waste of volunteers' time and good faith.

III. Implementation:

To ensure timely resolution of and/or treatment for any physical, social or ethical harms, each HVTU must have a system in place to identify, examine, report, and resolve harms that may arise as a result of trial participation. The PI will develop a plan for sharing information with local CAB / community representatives.

The HVTN Core will provide technical assistance and monitor plans for:

- developing mechanisms for identifying, reporting, and mitigating research harms;
- training staff to assist them in identifying, assessing and managing incidents of research harms;
- assessing participant comprehension of potential research risks and benefits;
- ensuring confidentiality of study data and test results - provision of confirmatory HIV testing; and
- developing an appeals system for trial participants who believe they have not received adequate response and/or resolution to issues raised.

4. Materials Development and Dissemination

I. Policy:

Each HVTU will accumulate and disseminate culturally and linguistically appropriate and relevant educational materials pertinent to vaccine research,

II. Rationale:

Designing, developing and disseminating culturally and linguistically appropriate and relevant educational materials pertinent to vaccine research; protocol development; the processes of informed consent and potential harms resulting from research participation; and the challenges and benefits of conducting community-based research, particularly related to community relations, readiness, and preparedness for clinical trials demonstrates good clinical practice.

As noted in the UNAIDS Vaccine Research Guidance Document, “Appropriate risk-reduction counselling and access to prevention methods should be provided to all vaccine trial participants, with new methods being added as they are discovered and validated.”

III. Implementation:

HVTN will develop a process and time-line for creating, translating and disseminating materials prior to the start of each protocol. Funds will be allocated in the budget submitted by all sites for materials development and dissemination. At all local sites, working collaboratively with members of the community, efforts should be taken to assess and identify the appropriate type of educational materials needed. This will include those material which need to be developed to accurately educate potential trial participants and the community at-large about the research agenda of the network and the processes and technical aspects of the research being conducted at local sites. Where appropriate, all information should be developed at appropriate reading levels and translated into applicable languages. Community members must be engaged to evaluate materials prior to mass dissemination. Information pertaining to the initiation and ongoing implementation of studies should be disseminated broadly and in a timely fashion that will enable study participants, CAB members, and identified infected and affected communities to remain informed about and engaged throughout the research process. This includes dissemination of trial results to each community contributing cohort members.

5. Collaboration and Partnership Development

I. Policy:

Each HVTU will develop local partnerships that ensure community participation in vaccine research.

II. Rationale:

HIV research, particularly vaccine research, is by necessity, a broad and interdisciplinary activity. The expertise to successfully conduct HIV research requires more than a simple understanding of how to conduct the clinical aspects of trials. Indeed, the range of behavioral, political, social, legal, and psychological issues particularly raised by vaccine research requires not only broad expertise, but active collaborations with other community groups and resources which can assist trial sites, trial participants and communities affected by vaccine research in dealing with these issues. In particular, HIV vaccine research requires a close degree of communication and collaboration with communities of color which have suffered from long-standing and diverse forms of harmful discrimination in both medical research and clinical practice, while also bearing a disproportionate burden of HIV infections.

The goals of these collaborations will be somewhat different, depending on the community. Overall, the goals of community collaborations should be:

- To leave the communities better off than when the research began, regardless of the ultimate result of any particular vaccine trial.
- To create community investment in research, and to take a long-term approach to fostering community relationships.
- To make the research an activity which not only benefits the world, or science, but also the specific communities in which it takes place.

III. Implementation:

Research sites must demonstrate their ability to maintain informal and/or formal ongoing and substantive relationships with community groups and advocates. They should realistically plan for how they will work to nourish these relationships. This should include, but must be more than, quickly reporting relevant local data to interested local parties. The evidence of collaborative relationships must be more than basic letters of support, and must speak to the actual potential results of these relationships. Success is demonstrated when the research site is known in the community in which it is located; civic leaders, local media and key informants in the community will value the site's presence in concrete ways. The research site is known to work for the direct and immediate benefit of the community.

6. Issues Management

I. Policy:

Each HVTN research site will develop a clear plan for managing issues. Establishing a state of readiness requires site staff engage in a process that will create awareness of, and sensitivity to, potentially controversial issues.

II. Rationale:

Politically charged, medically and legally complex and, psychosocially intricate, community-based research on HIV/AIDS, particularly vaccine research, has generated unprecedented debate, passionate activism, and emotionally charged public discourse. Volatile issues that can arise from the public circulation of misinformation in the media or other forms of mass communication, about the nature of the research; the products or interventions being tested; the treatment of trial participants; or the conduct of researchers in communities during the course of designing, developing and implementing community-based HIV/AIDS research, is a critical area for HVTN sites to be prepared for.

Ongoing assessment of the information and educational needs of the community, consistent and frequent communication with trial participants and the community-at-large about the status of the research being conducted, and building the capacity necessary to manage issues associated with the research that may arise is at the core of issues management.

III. Implementation:

Success in conducting this type of research requires a certain degree of public confidence and trust. Therefore, sites conducting research will take the steps necessary to identify, confront, manage and resolve unforeseen issues that may impact public confidence in the site and the research being conducted throughout the course of the project. Working with staff and through community contacts, sites should try to determine any potential controversial issues and evaluate their capacity to respond appropriately. Does the site have the necessary infrastructure, staff, resources, equipment, internal and external relationships (such as those with local and/or national media) to respond to issues? With a clear understanding of the site's state of preparedness, a written issues management plan should be developed that will outline a decision-tree for implementing the plan, the staff roles and responsibilities in managing issues including the key contact for decision making, and the available and accessible mechanisms for rapid internal and external communication.