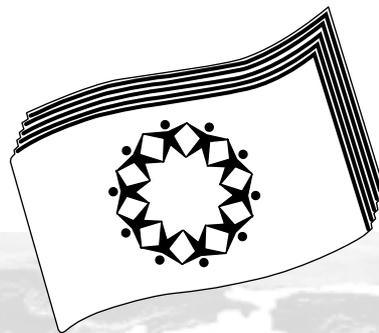


# Developing Vaccines to Prevent HIV and AIDS

*An Introduction for Community Groups*



International  
**C**ouncil of  
**A**IDS  
**S**ervice  
**O**rganizations

JULY 2000

## Developing Vaccines to Prevent HIV and AIDS: An Introduction For Community Groups

This publication is intended to promote and support the role of community-based organizations around the world in their involvement in HIV/AIDS vaccine research. It is a starting point that can be adapted to suit different the needs of countries and communities.

Published by the International Council of AIDS Service Organizations (ICASO). Copyright (c) 2000 by the International Council of AIDS Service Organizations.

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# ICASO

ICASO is the international network for community-based AIDS organizations (CBOs) whose mandate is to promote and support the work of CBOs around the world in the prevention of AIDS and care and treatment for people living with HIV/AIDS, with particular emphasis on strengthening the response in communities with fewer resources and within affected communities.

ICASO unites groups throughout the world who have been affected by the HIV/AIDS epidemic.

ICASO's recognition and respect for the human rights of all persons is central to an intelligent public health strategy to combat the AIDS epidemic.

The ICASO network is an interactive global focus point in the international HIV/AIDS world, gathering and disseminating information and analysis on key issues, coordinating the development of CBO/NGO positions on these issues, and working as partners with key international agencies to ensure that the concerns and interests of CBOs and NGOs around the world are articulated and represented at all levels.

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## Why Do We Need an HIV Vaccine?

The human toll of AIDS is staggering. Over 16 million men, women and children have died from AIDS. More than 33 million people are living with HIV. Each day, another 15,000 people are infected.

AIDS is overwhelming health care systems and national economies. More than 95% of all new infections are in developing countries, making HIV/AIDS a serious threat not only to global health, but also to global development. According to the United Nations, medical and human costs of AIDS have actually reversed economic and social development in several countries.

Current prevention efforts - including condom education, clean needle distribution, peer counselling, providing HIV treatments to reduce mother to child transmission, and making blood supplies safer - have slowed the spread of HIV, but have not stopped it.

Current treatments are inadequate because they do not lead to a cure; at best, they slow disease progression. They are complicated to administer, require close medical monitoring, and can cause significant side effects. They are also very costly and, as a result, are inaccessible to the majority of people living with HIV/AIDS.

The best long-term hope for controlling AIDS is the development and widespread distribution of a safe, effective and affordable preventive vaccine. The world community has embraced the goal of developing a safe and effective vaccine by the Year 2007. This will require both scientific breakthroughs and increased financial and political support from governments, pharmaceutical companies, international agencies, communities and individuals.

The global burden of disease and death related to HIV is increasing at a rate unmatched by any other pathogen. For many countries, it is already the leading cause of death. Currently available treatments are...not readily available to the vast majority of people affected by HIV/AIDS. These are people living in developing countries and in marginalized communities in developed countries. There is therefore an ethical imperative to seek, as urgently as possible, a globally effective and accessible vaccine, to

complement other prevention strategies. Furthermore, this ethical imperative demands that HIV preventive vaccines be developed to address the situation of those people and populations most vulnerable to infection.

*Ethical Considerations in HIV Preventive Vaccine Research: A UNAIDS Guidance Document, Joint United Nations Programme on HIV/AIDS (UNAIDS)*

## How Can this Document Be Used to Promote HIV Vaccine Development?

Development of a safe and effective HIV vaccine involves many years of research. This research is underway now, but much more needs to be done. The current rate of progress will not result in a vaccine in the near future. More organizations and individuals need to become involved in promoting HIV vaccine development.

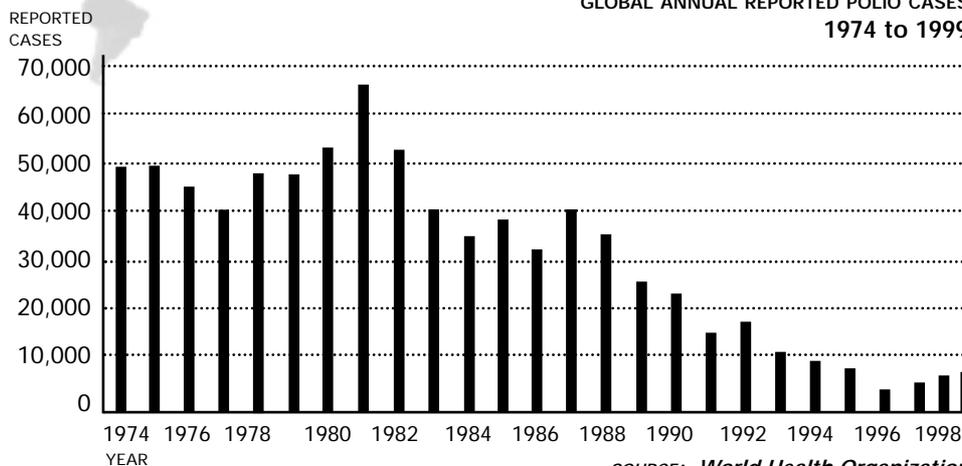
This document provides a basic introduction to HIV vaccine development. Organizations and individuals can use this document in one or more of the following ways (depending on their level of knowledge and experience):

- As a way to start learning about what vaccines are and how they are developed. This document provides basic information and it lists sources for additional information.
- As a way of sharing information with others. This document can be used to inform other organizations and the general public about HIV vaccine issues.
- As a way of determining how to participate in the international HIV vaccine development effort. This document describes some of the ways that individuals and organizations can become more involved in the process.
- As a way to begin defining questions, concerns, and policy issues. Organizations and individuals that want to do advocacy work around HIV vaccine development can use this document to begin to define advocacy positions.

Readers who would like more detailed information on HIV vaccine development should consult the list of resources at the end of the document.

## An Introduction to Vaccines

Vaccines save millions of lives each year and prevent many more people from getting sick. They are one of the most powerful and cost-effective health interventions available today. For example, extensive use of the smallpox vaccine eradicated that disease from the world. As well, widespread vaccination against polio has reduced the number of cases of disease dramatically (see chart); today, the Western Hemisphere, Europe, and many parts of Asia are free from polio.



Vaccines exist for many other diseases including measles, chicken pox, influenza, hepatitis A and B, mumps, pertussis and rubella. However, there are a number of important disease for which there is no effective vaccine, including HIV/AIDS, malaria and tuberculosis.

When properly manufactured and used, vaccines are among the safest of medicines. Vaccine safety is ensured by undertaking extensive research in laboratories, animals and human volunteers before the vaccine is widely used. As well, after a vaccine is approved for public use, its safety is continuously monitored by national and international health agencies.

**Exactly what are vaccines?** A vaccine is a substance that teaches the body's immune system (the body's mechanisms for fighting disease) to recognize and protect against a disease caused by an infectious agent or virus. When people are given a vaccine against disease X, this provokes a response from their immune systems. The immune systems are then "on alert." If these people are later exposed to disease X, their

immune systems are ready to fight the disease.

**Is a vaccine a cure?** Most of the time, when we talk about vaccines we are referring to preventive vaccines - i.e., medicines that protect people who do not have a disease from getting that disease. These vaccines do not provide a cure. A cure would help people who are sick or who already have a disease to recover. Scientists are also trying to develop what are called "therapeutic vaccines" for HIV, hepatitis, cancer, addiction and a number of other conditions. Therapeutic vaccines are designed to treat disease, not to prevent it. However, therapeutic vaccines for HIV are still very much in the early stages of development; no product has been licensed for use. In this document the term vaccine is used to refer to preventive vaccines, not therapeutic vaccines.

**How likely is it that a preventive HIV vaccine will be developed?** The consensus is that the scientific progress over the last decade has now made a vaccine against HIV an achievable goal. Non-human primates have been protected by experimental vaccines, and a number of candidate vaccines have been shown to be safe in Phase I trials and to trigger immune responses. However, it is also important to note that vaccine development is a long and complicated process, and that the first generation of HIV vaccines are likely to be only partially effective - i.e., they will not prevent AIDS in everyone who is vaccinated and exposed to HIV.

**Is there any risk of becoming infected from an HIV vaccine?** There are a number of different approaches used to make vaccines. Two of the most common approaches use killed or weakened bacteria or viruses. Currently, no company is pursuing either of these strategies because of the risk that a small amount of HIV may not be adequately killed or weakened (and could therefore result in the vaccine actually infecting someone with HIV). Instead, companies and research agencies are focussing on approaches that only small components of the virus that cannot cause disease.

### An Ideal Vaccine

An ideal HIV preventive vaccine would:

- be effective regardless of the nutritional and health status of the target population and ethnicity;
- protect individuals against all subtypes of HIV;
- protect against any route of HIV infection;
- be inexpensive to manufacture;
- be easy to transport and administer;
- be stable under field conditions; and
- provide long lasting protection - i.e., require few (if any) follow up inoculations.

Given the rate of spread of HIV worldwide, even a less-than-ideal vaccine that is only 50% effective would provide substantial public health benefit and help contain the epidemic.

*Adapted from Scientific Blueprint for AIDS Vaccine Development  
International AIDS Vaccine Initiative*



## Vaccine Development

Vaccine development is a lengthy process of testing ideas and products. Vaccines are developed through a series of experiments designed to answer scientific questions and evaluate possible vaccine concepts. This research effort involves a number of different players from the private and public sectors - scientists and clinicians working in private companies and research agencies, government officials and community groups. Vaccine concepts are usually tested and improved many times before they are ready for use. This process of developing ideas into usable vaccines can be divided into five stages. They are described below (using HIV as an example):

### **Idea Generation (Basic Science).**

The first stage of vaccine development occurs in universities, research institutes and private companies. Scientists working with existing scientific knowledge and laboratory tools develop ideas for how an HIV vaccine could function. They examine cells from the human immune system and parts of the AIDS virus for clues about what might work and how a vaccine might be designed. Hundreds of scientists all over the world are now contributing to this stage of vaccine development. Many new designs are generated each year; only a very small number move forward to the next stage.

### **Pre-Clinical Development.**

In the second stage, scientists test vaccine preparations in cell-culture. If the results are promising, the vaccines are then tested in animals. Animals are used at this stage to see if the vaccine is safe and if it works in the way scientists believed. Scientists also use the information from animal studies to improve the design of the experimental vaccines. Only a small percentage of the vaccines that make it to the pre-clinical development stage are deemed to be safe enough and promising enough to be evaluated in people.

### **Clinical.**

If a vaccine is found to be safe and promising in laboratory and animal testing, it moves to the third stage: clinical trials in humans. Human testing involves three different phases of clinical trials. The whole process can take many years. Human testing is discussed in detail in the next section.

### **Licensing.**

If the clinical trials are successful and the company decides to market the vaccine, it first has to obtain a licence. This involves making an application to the department of government responsible for regulating pharmaceutical products. If the company wants to sell its product in many different countries, it will usually have to obtain licences in each of these countries. This process can take several years.

### **Delivery.**

If a safe and effective HIV vaccine for people can be developed, the challenge will be to produce it and to get it to people who need protection from HIV. Historically, delivery of vaccines to people around the world has proved to be a difficult task. In fact, even today many safe and effective vaccines are unavailable to most people in the world. It is now nearly 20 years since the Hepatitis B vaccine was licensed and yet only 30% of the newborn infants in the world are receiving it. Delivery of safe, effective vaccines is a key component of the HIV vaccine development effort.



## Testing HIV Vaccines in Humans

Any new vaccine, no matter how promising it appears in laboratory and animal testing, has to go through a careful process of clinical trials in humans before its usefulness can really be determined. A clinical trial is a research study used to assess the benefits and risks of a new vaccine (or treatment). Clinical trials are conducted in three sequential steps or phases (see box).

### The Three Phases of Clinical Trials

#### Phase I Trial

A clinical trial with a small number (usually 60 or less) of healthy volunteers, typically at low-risk for HIV infection. Phase I trials test a vaccine's safety in humans, including its metabolic and pharmacologic actions and any side effects seen with increasing doses. Phase I trials usually last 12-18 months.

#### Phase II Trial

A controlled clinical trial which is designed to identify common short-term side effects and risks associated with the test vaccine and to collect preliminary indications of its potential efficacy (i.e., its ability to prevent infection). Phase II trials enroll between 50 and 500 volunteers with characteristics similar to the population for whom the vaccine is being developed. Phase II trials generally have two or more arms and last about two years.

#### Phase III Trial

A large controlled study to determine the efficacy of the test vaccine at an optimally selected dose and schedule. Phase III trials also gather information about safety needed to evaluate the overall benefit-risk relationship of the vaccine. They usually include several thousand volunteers from the population for whom the vaccine is intended and last 3-4 years.

*Adapted from the website of the International AIDS Vaccine Initiative*

The detailed plan for a trial is called a protocol. The protocol lays down procedures for how the vaccine will be given, who is eligible to take part, what the timetable is for tests and clinical visits by participants, how long the study will last, how the results will be assessed, and so forth.

To determine the efficacy of an HIV vaccine in a clinical trial, researchers randomly divide the participants into two groups: one that will receive the vaccine plus HIV prevention efforts (the vaccine group), and one that will receive a "control" plus HIV prevention efforts (the control group). The control group may receive a placebo (an inactive substance), or another HIV vaccine that is known to be effective (if one has been developed), or a vaccine for another condition other than HIV. Randomization is the best way to make sure that people in different arms of the trial are broadly similar, so that the effects of the vaccine can be reliably measured.

In some trials, neither the researchers nor the participants are supposed to know who is getting the vaccine. This is called double-blinding. (If only the researchers know who is getting the vaccine, this is single-blinding.) The purpose of blinding is to make sure that no one's expectations colour the results of the trial.

To determine how effective the vaccine is, the scientists and clinicians involved in a Phase III trial need to monitor the health of the two groups for a period of time, usually several years, keeping track of how many volunteers get HIV despite the trial's prevention efforts. The researchers then compare the results in the two groups. If fewer people get HIV or AIDS in the vaccine group than in the control group, then the vaccine can be declared at least a partial success.

## Current Status of HIV Vaccine Trials

In the 15 years since HIV was identified as the cause of AIDS, over 30 candidate vaccines have been tested in Phase I trials. Only one vaccine concept, however, has progressed to Phase III efficacy trials and only two other concepts have reached the stage of Phase II trials. The vaccine concept currently in Phase III trials is a recombinant subunit vaccine produced by VaxGen. Two Phase III trials are under underway with this product. One trial is being conducted in Canada, the Netherlands, Puerto Rico and the United States, primarily in men who have sex with men, using a vaccine based on HIV subtype B. The other trial is being conducted among intravenous drug users in Bangkok, Thailand, using a vaccine based on HIV subtypes B and E. Results from these trials should be available in late 2002 or early 2003. Initial results are expected to be available at the end of 2001.

To date, the vast majority of the clinical trials have been conducted in developed countries. With few exceptions, the vaccine products that have been tested have been based on HIV subtype B, the subtype of HIV that predominates in North America, Europe, Latin American, Australia and New Zealand. Subtype B accounts for only a small percentage of new infections each year. So far, no HIV vaccines have been tested that are based on the two most prevalent subtypes of HIV (A and C) which, together, account for about two-thirds of all HIV infections worldwide. At this time, it is not clear just how important HIV subtypes are for vaccine design. However, in the absence of definitive data on the immunological significance of the different subtypes, candidate vaccines tested in individuals at risk for HIV infection (i.e., Phase II and III trials) should be based on the HIV subtypes that predominate in the proposed trial population.

The following table records the trials that have been conducted or are being conducted in developing countries.

### HIV Vaccine Trials in Developing Countries

COUNTRY	VACCINE APPROACH	TYPE OF TRIAL	SPONSORING COMPANY OR ORGANIZATION	YEAR TRIAL STARTED
Brazil	Synthetic peptide <i>MN-V3 branched</i>	Phase I	United Biomedical Inc.	1994
China	Synthetic peptide <i>MN-V3 branched</i>	Phase I	United Biomedical Inc.	1993
Cuba	Recombinant subunit <i>V3 protein</i>	Phase I	Centro de Ingenier a Genética y Biotecnología	1996
Thailand	Synthetic peptide <i>MN-V3 branched</i>	Phase I	United Biomedical Inc.	1994
	Recombinant subunit <i>gp120-MN</i>	Phase I	Genentech/VaxGen	1995
	Recombinant subunit <i>gp120-SF</i>	Phase I	Biocine/Chiron	1995
	Recombinant subunit <i>gp120-SF2 (B-SI)</i> <i>gp120-CM235 (E-NSI)</i> <i>and combinations of both</i>	Phase II	Chiron Vaccines	1997
	Recombinant subunit <i>gp120-MN (B-SI)</i> <i>+gp120-CM244 (E-NSI)</i>	Phase II	VaxGen	1998
	Recombinant subunit <i>gp120-MN (B-SI)</i> <i>+gp 120-CM244 (E-NS)</i>	Phase III	VaxGen	1999
Uganda	Live vector <i>Canarypox-env/gag/pol (B)</i>	Phase II	Pasteur-Mérieux-Connaught	1999

*Source: UNAIDS*

This Table lists the range of vaccine approaches that have entered clinical trials in developing countries. Information on these different approaches can be found from a number of sources including the US National Institutes of Health (NIH) and the International AIDS Vaccine Initiative (IAVI).



## Ethical Issues in HIV Vaccine Trials

Organizations and individuals involved in HIV vaccine clinical trials need to be able and willing to address the difficult ethical concerns that arise during the development of HIV vaccines. Here is a description of some of the more common issues.

### **National and Community-Level Decision-Making.**

A central factor in ethical HIV vaccine development is the ability of host countries and communities to be involved in a meaningful way in decisions made about the trials, to ensure the scientific and ethical conduct of vaccine research, and to function as equal partners with pharmaceutical companies and others in a collaborative process.

### **Community Involvement.**

The relevance of HIV vaccine research to affected communities, and the acceptance of trials by the communities where the trial is being conducted, are central to ethical vaccine development. Community representatives should be involved in an early and sustained manner in the design, development, implementation and dissemination of results of HIV vaccine research.

### **Ethical Review.**

A plan for monitoring the initial and continuing adequacy of the informed consent process and risk reduction interventions, including counselling and access to prevention methods, should be developed at the outset. Before a trial can begin, an ethics committee must approve the protocol. The ethics committee is responsible for protecting the rights and interests of the people in the trial. It should function independently of the people running or financing the trial.

### **Informed Consent.**

For a clinical trial to be ethical, researchers must first obtain the informed consent of each participant. Volunteers need to understand the risks and benefits associated with participation in the trial. They also need to know that they have the right not to participate or to withdraw at any time. The researchers must fully describe the study and obtain the agreement of the participants to take part. The researchers must explain to participants a number of important things about the trial, including its purpose, the vaccine that will be tested, the number of clinical visits, and possible benefits and harms.

### **Access to HIV Prevention.**

An essential requirement of any vaccine trial is that all volunteers in the study must receive the best available counselling and education on how to stay healthy and avoid HIV.

### **Access to Treatment.**

Care and treatment for HIV and its associated conditions must be provided to participants in HIV vaccine trials. Ideally, the best proven therapies should be provided. If that is not possible, participants are entitled to the highest level of care attainable in their country.

These ethical issues are among 18 guidance points included in Ethical Considerations in *HIV Preventive Vaccine Research: A UNAIDS Guidance Document*, issued by the Joint United Nations Programme on HIV/AIDS (UNAIDS).

In addition to the ethical consideration outlined above, HIV vaccine development and testing may have a broader impact on HIV prevention and education campaigns, and other HIV-related efforts. When preparing and running a vaccine trial, every attempt should be made to create a supportive environment for those involved in the trial and for the community they came from, and to minimize potential adverse effects.



## Community Participation

Involvement by individuals and community groups in HIV vaccine development is critical to the success of the HIV vaccine effort. This section provides reasons why communities should be involved and ways in which they can participate in HIV vaccine trials. It also presents a list of questions community groups can ask researchers involved in the trials.

Community representatives can help to ensure that HIV vaccine research is firmly established on the

international agenda and, once a vaccine is developed, that it will be available in those countries where it is most needed. As well, community representatives have an important role to play in all stages of the design, planning and implementation of HIV vaccine trials and in the dissemination of results from these trials.

The involvement of community representatives will help to make volunteers more comfortable with the trial and increase their commitment and follow-up rates.



## What Can Community Representatives Do?

At the national level in countries where trials may take place (usually referred to as “host countries”), community representatives can work with others within their country and internationally to assess how the country can and should participate in HIV vaccine development activities. This could involve:

- identifying resources;
- establishing partnerships;
- conducting national information campaigns; and
- strengthening scientific and ethical committees.

Even in countries where vaccine trials are unlikely to be conducted, it is important that communities understand the vaccine development process and the time considerations. Because vaccine development takes a long time, it is important to ensure that there is no lessening of commitment to safe behaviours by people at risk for HIV who might think that because there is a vaccine trial, there is effective prevention for HIV.

Once a decision is made to conduct a trial in a country, community representatives have a key role to play in planning and implementing the trial, in ensuring the ethical and scientific quality of the proposed research, and in ensuring its relevance to the affected community.

Community representatives can facilitate the collection of information on risk behaviours, information that is important for interpreting the data generated by trials. This will help to improve the quality of the trial.



## How Can Communities Become Involved?

In communities where trials are being planned, community representatives should:

- participate in scientific and ethical committees reviewing proposed HIV vaccine research protocols;
- work with researchers, sponsors and regulatory bodies to design a culturally informed consent strategy and process;
- share information with communities where the trial is being planned on the HIV vaccine development process and clinical trials;
- relay community concerns to scientists and clinicians involved in the trial;
- ensure that the media is well informed about the planned trial; and
- be involved in discussions on who will bear the costs for participants in the trials and on what level of care and treatment they will receive.

Participation of the community in the planning and implementation of a vaccine development strategy can provide the following benefits:

- information regarding the health beliefs and understanding of the study population;
- input into the design of the protocol;
- input into an appropriate informed consent process;
- insight into the design of risk reduction interventions;
- effective methods for disseminating information about the trial and its outcomes;
- information to the community-at-large on the proposed research;
- trust between the community and researchers;
- equity in choice of participants;
- equity in decisions regarding level of standard of care and treatment and its duration; and
- equity in plans for realising results and vaccine distribution."

*Ethical Considerations in HIV Preventive Vaccine Research:  
A UNAIDS Guidance Document,  
Joint United Nations Programme on HIV/AIDS (UNAIDS)*

Once the trial is on-going, community representatives should:

- monitor the trial recruitment process to make sure that volunteers fully understand the risks and benefits of participating;
- ensure that the community is kept well informed about the trial;
- relay community concerns to the scientists and clinicians involved in the trial;
- create a supportive environment for those involved in the trial and for the communities they come from;
- act as an information resource for other community groups, other stakeholders and the media; and
- work to minimize the risk of an increase in transmission rates associated with participation in the trial or knowledge that a vaccine trial is being conducted.

Another way for community representatives to become involved is by working with and informing communities. Community education is needed now to prepare people for the research process, and to lay the foundation for vaccination programmes in countries around the world. Community representatives can accomplish this by:

- **Assessing and shaping current attitudes and awareness about HIV vaccines.** Discuss HIV vaccines with people. Help them understand the role vaccines might play in controlling HIV/AIDS. Use local meetings and networks as an opportunity to discuss vaccine development. Address people's fears.
- **Linking with local, national and global information sources.** Internet-based resources are an excellent way to find information on HIV vaccine development (see the list of websites at the end of this document). At the local level, develop links with medical centres, ministries of health and others involved with AIDS vaccine development.
- **Sharing information.** The international effort to develop an HIV vaccine can benefit from the experiences of your community. Participating in local, national and international conferences, joining local HIV/AIDS prevention and care networks, and publishing in newsletters and on websites are good ways to share information. It is also important to contact local media and make sure they are well informed about vaccine development.
- **Integrating knowledge about vaccine development into HIV/AIDS prevention messages.** Vaccine development should be viewed as one part of a broader HIV/AIDS prevention effort. Use existing community outreach networks to discuss HIV vaccine development.



## What Do Community Representatives Need to Know from Researchers?

Below is a list of questions community representatives can pose to researchers during the design, development and implementation of a clinical trial and during the dissemination of results from the trial. Posing these questions to researchers (and getting answers) will help to ensure that the trials are ethical and that all necessary preparations are in place. (This list is adapted from *Participating in a Clinical Trial*, by the National Institutes of Health in the United States).

### **What is the goal of this research study?**

Why are you doing this study? What vaccines are you testing? What questions do you want to answer from this study? What will you do with the answers? Have you or others done this type of research before? In this country and in this community? What did you learn then, and how did you share your discoveries with the research volunteers and the community?

### **Who is responsible for this study?**

Who is running this study? Whose idea was this study? Were people like me a part of putting it together? Who are the researchers? Are they doctors or scientists? Who do they work for? Have they done studies like this before? Is my government a part of this study? Who else is a part of this study? Who is paying for this study? Who will make money from the results of this study?

### **How are communities involved in this study?**

How will the study be explained in my community? Aside from the government and researchers, who reviewed the study before it started? Who else in the community did you talk to? Do you have a Community Advisory Board (CAB) or other open process where people can get information? Who is on your CAB? When does it meet? Where? Whom from the study can I go to with ideas, questions, or complaints? How will people like me find out about how the study is going?

### **Who is being recruited for this study?**

What kinds of people are you looking for? Why? Are you recruiting people less than 18 years of age? Are you recruiting people who cannot say no because of their job or for other reasons? How are you finding people for this study? Will you answer questions before a volunteer signs the consent form? Can a volunteer quit the study at any time?

### **What are the benefits to research volunteers?**

Is payment involved? How will volunteers be paid? Will volunteers get free health care or other services if they participate? For how long? Will volunteers get general health care and psychological care if they participate? For how long?

### **How will volunteers be protected from harm?**

Do volunteers stand a chance of being harmed during this study? In the future? Does the study protect volunteers from all types of harm? Will all volunteers get treated equally? If volunteers are harmed, who will take care of them? Will they get needed treatment and care? Who pays for their treatment and care? How will my organization or my community learn about any risks or harms faced by volunteers?

### **How will privacy be protected?**

Who is going to see the information? Will names be used with the information? What happens to the information on volunteers who quit the study? Is there a written guarantee of privacy?

### **What will happen when this research study is completed?**

What will you do with the results of the study? How will the public learn about the results? Will you send volunteers a copy of the results? When? What other studies are you planning to do in my country and in my community?

## **Resources**

The following organizations are a good source of information on HIV vaccine development:

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### **The WHO-UNAIDS HIV Vaccine Initiative**

World Health Organization / UNAIDS  
20 avenue Appia  
1211 Geneva 27, Switzerland

Tel: (41) 22 791 34 84

Fax: (41) 22 791 48 65

[www.unaids.org](http://www.unaids.org)

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### **The International AIDS Vaccine Initiative**

110 William Street, 27th Floor  
New York, NY 10038-3901  
United States

Tel: (212) 847-1111

Fax: (212) 847-1112

[www.iavi.org](http://www.iavi.org)

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## Websites with Information on HIV Vaccine Development

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### African AIDS Research Network

[www.refer.sn/sngal\\_ct/rec/rars/rars.htm](http://www.refer.sn/sngal_ct/rec/rars/rars.htm)

This Senegalese organization maintains a French-language website.

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### Africa News

[www.africanews.org](http://www.africanews.org)

An English-language website with African media coverage of HIV-related developments.

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### AIDSfonds

[www.aidsfonds.nl](http://www.aidsfonds.nl)

This Dutch AIDS organization posts useful AIDS vaccine information on its website in support of its mission to “work toward a world without AIDS.”

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### AIDS Vaccine Advocacy Coalition

[www.avac.org](http://www.avac.org)

AVAC is an advocacy group in the United States that publishes an annual review of progress in HIV vaccine development. AVAC produced Community Perspectives in Participation in Research, Advocacy and Progress, a handbook on HIV vaccines, available on their website.

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### Centres for Disease Control

[www.cdc.gov/nip/publications/pink/](http://www.cdc.gov/nip/publications/pink/)

The United States government’s disease prevention agency website.

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### Family Health International

[www.fhi.org/en/aids/hivnet/hivnet.html](http://www.fhi.org/en/aids/hivnet/hivnet.html)

FHI administers the United States government’s international HIV vaccine research network.

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### Global Alliance for Vaccines and Immunization

[www.vaccinealliance.org](http://www.vaccinealliance.org)

GAVI provides information about delivery of vaccines with a particular focus on poor countries.

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### Grupo Pela Vidda

[www.pelavidda.org.br](http://www.pelavidda.org.br)

The website of this Brazilian PWA organization provides information in English and Portuguese.

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### Health Knowledge Network of South Africa

[www.healthnet.org.za/Modules/HIV\\_AIDS/hiv\\_aids.htm](http://www.healthnet.org.za/Modules/HIV_AIDS/hiv_aids.htm)

This site contains an extensive HIV/AIDS section.

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### International Council of AIDS Service Organizations

[www.icaso.org](http://www.icaso.org)

ICASO promotes and supports the work of community AIDS organizations around the world.

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### Joint United Nations Programme on HIV/AIDS (UNAIDS)

[www.unaids.org](http://www.unaids.org)

UNAIDS produced the publication Ethical Considerations in HIV Preventive Vaccine Research: A UNAIDS Guidance Document, portion of which are quoted or paraphrased in this text.

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### Medical Research Council of South Africa

[www.mrc.ac.za](http://www.mrc.ac.za)

This site contains information about the South African role in HIV vaccine development.

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### National AIDS Trust

[www.nat.org.uk](http://www.nat.org.uk)

The Trust promotes wider understanding of HIV and AIDS; supports efforts to prevent the spread of HIV; and works to improve the quality of life of people affected by HIV and AIDS.

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### National Institute of Allergy and Infectious Diseases, National Institutes of Health

[www.niaid.nih.gov/daids/vaccine/default.htm](http://www.niaid.nih.gov/daids/vaccine/default.htm)

NIAID is a research institute of the United States government. The site contains extensive information on international HIV vaccine development.

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### Pasteur Institute

[www.pasteur.fr](http://www.pasteur.fr)

A leading HIV vaccine research organization. In Paris, France.

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### University of California at San Francisco

<http://hivinsite.ucsf.edu/topics/vaccines/>

UCSF’s HIVinsite web page contains extensive information, including some in Spanish.

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### Resolving legal, ethical and human rights challenges in HIV Vaccine Research

[www.aidslaw.ca/durban2000/e-durban2000.htm](http://www.aidslaw.ca/durban2000/e-durban2000.htm)

This discussion paper published by the AIDS Law Project (South Africa) and the Canadian HIV/AIDS Legal Network in preparation for the Satellite “Putting Third First” they co-hosted in Durban (July 2000) will be updated with the discussions from that event. Available on the Web in English and French.

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# Communities in Action to Break the Silence



International  
Council of  
AIDS  
Service  
Organizations