



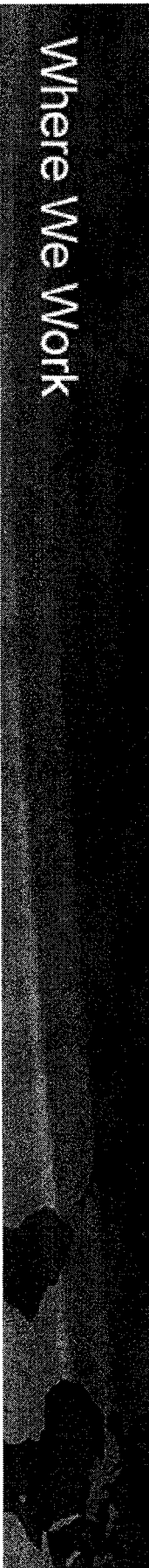
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- [VaxLit Toolkit](#)
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IAVI recognized early on that to develop effective AIDS vaccines for use throughout the world, it would be essential to build partnerships and bolster capacity to conduct vaccine trials at the highest technical and ethical standards in developing countries, where the need for a vaccine is greatest.

Today, a network of independent but interconnected research centers in five sub-Saharan African countries (Kenya, Rwanda, South Africa, Uganda and Zambia) play a central role in IAVI's vaccine development program, testing HIV vaccine candidates and conducting epidemiological studies that inform the design of candidates and provide baseline information for future efficacy trials. To date, IAVI and its network of partners have:

- Developed and advanced 13 HIV vaccine candidates into early-stage human trials, including the first HIV vaccine trials conducted in Kenya, India, Germany, Zambia and Rwanda
- Conducted 15 observational epidemiological studies
- Provided voluntary testing and counseling to more than 235,000 individuals in Africa

This partnership-based approach emphasizes building capacity by training local researchers and developing the infrastructure required for all such research. Investigators within this network are linked to scientific consortia—such as the Center for HIV/AIDS Vaccine Immunology and the Neutralizing Antibody Consortium—and collaborate closely with IAVI researchers.

To learn more about the clinical trials and epidemiological studies conducted at these clinical research centers, visit the IAVI Studies Database.



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# What We Do

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## CLINICAL RESEARCH STANDARDS

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and our partners reach out to surrounding communities to educate participants about HIV vaccine research. IAVI also solicits and takes into account the advice of community representatives through Community Advisory Boards on various aspects of our clinical research studies, such as recruitment procedures and the language used in the informed

In preparing for clinical trials and related observational epidemiological studies, we

Volunteers are the foundation of our clinical trials: their rights, dignity, confidentiality, health and welfare are protected at all times.

consent process.

IAVI has instituted procedures and practices to ensure that volunteers clearly understand their rights and obligations as participants in clinical research. Trial information is continually reviewed with volunteers throughout the course of the trial, and informed consent materials and processes employed by IAVI and its partners are tailored to local cultural contexts. Exit interviews also are often conducted with volunteers as part of an ongoing quality improvement process.

Volunteers receive access to high-quality medical services while participating in trials, including voluntary HIV counseling and testing (VCT), basic health care, HIV risk-reduction, family planning counseling, and, should the need arise, referrals for HIV treatment or more complex medical problems. IAVI works with research partners to develop and implement procedures for working with women, as well as men who have sex with men, in a manner that minimizes the difficulties and social risks associated with participating in HIV vaccine research.

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## CLINICAL RESEARCH STANDARDS

IAVI has published several toolkits to provide guidance to individuals engaged in clinical and epidemiological research.

IAVI receives guidance in the conduct of clinical research from standard local, national and international sources, including:

- The International Conference on Harmonization's Good Clinical Practice
- United States Federal Policy for the Protection of Human Subjects (The Common Rule, 45 CFR Part 46)
- UNAIDS/MHO documents "Ethical considerations in biomedical HIV prevention trials" (2007) and "Good participatory practice: Guidelines for biomedical HIV prevention trials" (2011)
- Independent ethics committees (also called Institutional Review Boards) established by local and national governments, universities, hospitals, etc.
- Scientific and regulatory authorities that review trial protocols, informed consent forms and other study related materials
- Community Advisory Boards, which advise researchers on community issues, informed consent processes and other aspects of their work with volunteers

## RELATED PUBLICATIONS

[Clinical Guidance: Essential Approaches for the Conduct of IAVI Clinical Research](#)

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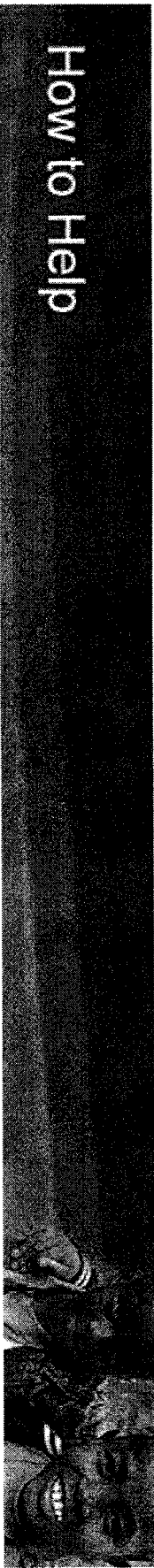
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leading infectious diseases. Yet devising an effective vaccine to prevent HIV remains one of the greatest scientific challenges of our time. Researchers have, however, made major progress in recent years toward developing such vaccines.

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Learn more about:

- HIV vaccine literacy and IAVI's comprehensive *VaxLit Toolkit*
- The HIV/AIDS pandemic, how vaccines work and types of vaccines
- HIV vaccine-related terms in a glossary authored by United States National Institute of Allergy and Infectious Diseases
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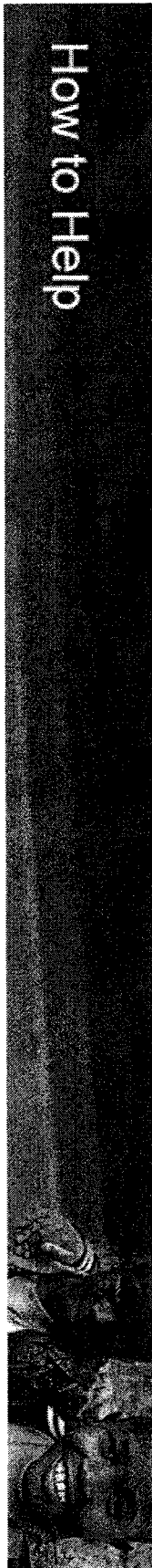
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## VACCINE LITERACY

IAVI and its partners strive to provide information to communities affected by HIV, particularly in developing countries, about AIDS vaccine development and the rights and responsibilities of participation in such research. These HIV vaccine literacy efforts help create an atmosphere supportive of vaccine development, prepare communities for the conduct of HIV vaccine research and help people make genuinely informed decisions about whether or not they will participate in those studies.

IAVI and its partners promote vaccine literacy in a broad range of audiences, including clinical research volunteers, advocates, medical professionals and journalists. In support of such work, IAVI's VaxLit Initiative has created a toolkit that advocates and research center staff can use to inform others about AIDS vaccine development and the processes essential to its rigorous and ethical conduct.

The VaxLit Toolkit—which includes a reference manual, a participatory training guide, fact sheets, powerpoint slides and a user guide—is written in language accessible to people with minimal education and no scientific background. It can be adapted to suit various cultural and linguistic contexts and is intended for use by the HIV and AIDS field at large, not just IAVI and its affiliated research centers.

## VAXLIT TOOLKIT

[Complete Toolkit](#)

[Reference Manual](#)

[Training Guide](#)

[AIDS Vaccine Research: FAQ \(fact sheet\)](#)

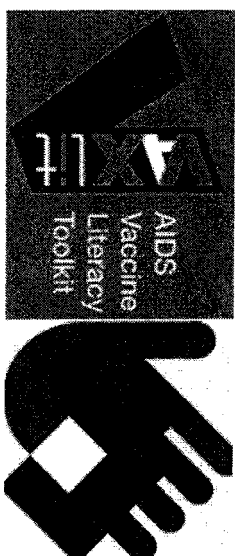
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IAVI and its partners use the toolkit to inform civil society groups about AIDS vaccine R&D, train trainers working in other HIV intervention programs, and to educate Community Advisory Board members, medical professionals and staff at clinical research centers.



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