

SOUTH AFRICAN AIDS VACCINE INITIATIVE GUIDELINES FOR COMMUNITY ADVISORY GROUPS (CAGs)

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The following guidelines were also consulted as part of the development of this document:

- The Medical Research Council *Guidelines on Ethics for Medical Research: HIV Preventive Vaccine Research*, Cape Town, Book 5, also available at: www.sahealthinfo.org/ethics on 1/7/2007;
- *The Adult AIDS Clinical Trials Group Guidelines for Community Advisory Boards*, updated 2/10/2000 at: <http://aactg.s-3.com/pub/docs/cabguide.htm#contents> on 1/7/2007; and,
- *The Hawaii AIDS Clinical Research Programme Community Advisory Board Guidelines* at: <http://www.hawaii.edu/hacrp/cabhaw.htm> on 1/7/2007.

These guidelines are endorsed by the National Department of Health.

INTRODUCTION

The South African AIDS Vaccine Initiative (SAAVI) is a lead programme of the South African Medical Research Council (MRC). SAAVI seeks to co-ordinate and provide the necessary support for the research, development and testing of HIV vaccines in South Africa. SAAVI has since its inception in 1999 supported community involvement in HIV vaccine development through the Masikhulwane Community Involvement Programme and its predecessors, the SAAVI Community Preparedness Programme and the South African HIV Vaccine Action Campaign (SA HIVAC).

HIV vaccine clinical trials are being conducted at a number of SAAVI trial sites. Masikhulwane provides support to these trial sites and trial site communities by supporting Community Advisory Groups (CAGs) [also known as Community Advisory Boards (CABs)], and in the co-ordination and maintenance of a SAAVI National CAG Forum which has met biannually since 2004.

Masikhulwane incorporates the notion of CAGs within its Community Involvement Model, in line with international practice on community involvement in HIV vaccine clinical trials.

BACKGROUND AND SCOPE OF THE GUIDELINES

Masikhulwane has consulted with the SAAVI National CAG Forum, and through the forum with CAGs, on guidelines that would provide a framework for CAGs in the SAAVI research system. Masikhulwane has also consulted with the Principal Investigators (PIs) of the SAAVI trial sites and the HIV/AIDS Vaccine Ethics Group (HAVEG) on the Guidelines. In addition, the Department of Health has participated in the National CAG Forum meetings where the Guidelines were discussed and in the drafting of the Guidelines.

The scope of these Guidelines includes the mission, setting up, roles and responsibilities, organisational arrangements, meeting procedures, secretariat and administrative arrangements, capacity building and development, outreach programmes and constitutions of CAGs, as well as the roles and responsibilities of the PIs, trial site units and Masikhulwane.

The Guidelines do not constitute a contract and are not legally binding. The Guidelines have now been adopted as SAAVI policy that applies to SAAVI-supported trial sites, although at this stage no enforcement mechanism, other than the persuasion of the parties concerned, exists. CAG Constitutions and any possible future Constitution or terms of reference of the CAG Forum will have to be harmonised with the Guidelines while at the same time permitting sufficient flexibility.

These Guidelines may contribute to the future development of guidelines by the Department of Health with more general application to CAGs beyond those involved in SAAVI. However, the CAG model is a relatively new component of the clinical trial system in South Africa and the CAGs and the National CAG Forum for HIV vaccine development are still in an early stage of development. It is therefore envisaged that the Model will develop further and that these Guidelines will be updated when necessary.

PREAMBLE

We - SAAVI Principal Investigators, Masikhulisane, CAGs, and the CAG Forum - the subscribers to these Guidelines,

- recognise the devastating impact of the AIDS epidemic on the people of South Africa and the urgent need for a safe, affordable, effective and locally relevant HIV vaccine;
- recognise the need to ensure that research does not result in exploitation of individuals and communities;
- recognise that the clinical research system requires approval of clinical research by the Medicines Control Council (MCC) and an Ethics Committee, and related research requires approval by an Ethics Committee; and,
- recognise the need for community involvement in HIV vaccine development to also include the proper functioning of CAGs as an integral component of the clinical research system.

We therefore endorse these guidelines so as to -

- contribute to meaningful community involvement in HIV vaccine research; and,
- support the development of a South African society working in a mutually beneficial and meaningful partnership with health researchers within a vibrant human rights environment.

I. DEFINITIONS

The term 'Community Advisory Group (CAG)' will be used as inclusive of the term 'Community Advisory Board (CAB)' and refers to both the general CAG and the adolescent CAG, unless the context indicates otherwise.

2. MISSION

CAGs provide an opportunity for affected communities, especially clinical trial participants to -

- (a) increase understanding of the clinical research process;
- (b) voice concerns about the development, implementation and outcomes of specific clinical and related studies;
- (c) give advice on accrual and retention of trial participants;
- (d) advocate for human rights and promote ethical conduct in clinical research; and,
- (e) contribute to addressing and resolving grievances about the research process.

3. ESTABLISHING AND MAINTAINING THE CAG

- (1) Each SAAVI-supported trial site unit must maintain a CAG and each SAAVI-supported trial site unit considering adolescent studies must strive to maintain an adolescent CAG.

- (2) Each CAG will be set up jointly by community representatives and PIs. This will be done through any locally accepted process. An example of such a process is: facilitating the election of representatives from a list of nominations from organisations and structures broadly representing the sectors of the trial site unit community, in a public meeting, taking into account the considerations listed in (3).
- (3) Community representatives on the CAG must be drawn mainly from the community surrounding the trial site, except for two resource persons who may be drawn from stakeholder institutions beyond this community.
- (4) Community representatives must broadly represent the sectors of the affected trial site or surrounding affected community. When electing the representatives, the following must also be considered: inclusion of people living with HIV/AIDS (PLWHAs); diversity in terms of gender, race and age; inclusion of marginalised members of the community; and the possible inclusion of trial participants.
- (5) CAGs, PIs, and other trial site staff must:
 - (a) Encourage active discussion and participation of CAGs in the whole process of HIV vaccine development (including protocol development, implementation, accrual and retention in trials, and results).
 - (b) Produce regular reports at each site on the progress of trials, and work towards solving problems of accrual and retention in trials, although CAGs will not participate directly in recruitment or retention.

4. ROLES AND RESPONSIBILITIES OF THE CAG

- (1) Each CAG will be guided by, but is not limited to, the following list of roles and responsibilities:
 - (a) Ensure information flow between investigators and participating communities, including to -
 - (i) facilitate information flow from the PIs to the community on the results of the research; and,
 - (ii) take responsibility for ensuring that information about HIV vaccine trials reaches the community.
 - (b) Education of the research team on community expectations, including to -
 - (i) help and advise researchers on the community entry process;
 - (ii) help and advise researchers on appropriate informed consent, recruitment and study-related documentation; and,
 - (iii) provide input into budgetary processes.

- (c) Education of the community on aspects of the research, including to -
 - (i) promote individual and organisational learning;
 - (ii) facilitate and conduct community awareness-raising and learning events on HIV and AIDS, and HIV vaccine development; and,
 - (iii) conduct outreach programmes for specific groups, e.g. adolescents.
 - (d) Voicing community concerns, including to -
 - (i) assess community impact of research trial protocols and studies;
 - (ii) formulate recommendations regarding the research agenda for HIV vaccine trials and related research; and,
 - (iii) ensure a community voice throughout the process of HIV vaccine development.
 - (e) Contribute to human rights compliance and ethical conduct of research, including -
 - (i) safeguarding the human and legal rights of trial participants and communities;
 - (ii) supporting the ethical conduct of HIV vaccine trial participants and those participating in related research; and,
 - (iii) giving advice with respect to trial protocols and studies, including the informed consent forms.
 - (f) Maintain a CAG handbook that consists of the CAG Guidelines, the (draft) Trial Participant Charter of Rights and other information about patients' rights, treatment guidelines, CAG rosters, nomination forms, links to HIV and AIDS resources on the web, and reading lists.
- (2) CAGs may advise on recruitment and retention plans, provide information to the community that enables different forms of involvement in HIV vaccine development, and refer potential trial participants to trial site recruiters. However, CAGs may not directly recruit participants into research.

5. SUPPORT FOR CAGs: ROLES AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS, SAAVI-SUPPORTED TRIAL SITE UNITS, AND MASIKHULISANE

- (1) The PIs will provide support to CAGs and support the participation of local CAG members in a National CAG Forum.
- (2) SAAVI-supported trial site units will provide administrative support to the local CAG, including but not limited to: reasonable costs for meetings, computer/Internet access, telephone, photocopying, fax usage, and postage.
- (3) Masikhulisane will provide support to CAGs and PIs at SAAVI-supported trial sites within the framework of these Guidelines, including enabling and providing support for a SAAVI National CAB Forum and mediation in any dispute between a CAG and PI.

6. ORGANISATIONAL STRUCTURE OF THE CAG AND THE CAG FORUM

- (1) The organisational structure of the CAG will be determined by the community members and as such may vary. The following must, however, be consistent:
 - (a) Each CAG must consist of no more than 20 members. Existing CAGs will be given a reasonable time period to comply with this provision.
 - (b) Membership of the CAG must be reviewed every two years.
 - (c) Resource persons will serve on the CAG for a predetermined period whereas specialists in any area of interest to the CAG may also be requested to attend CAG meetings occasionally.
 - (d) PIs, SAAVI or trial site staff, resource persons, and ad hoc specialists may not be voting members of the CAG.
- (2) Each CAG must designate three members to serve, preferably continuously for a period of two years, on the SAAVI National CAG Forum.

7. MEETING PROCEDURES OF THE CAG

- (1) Each CAG will meet at least six times a year although the frequency may be increased when necessary.
- (2) Each CAG member will receive an agenda prior to each meeting.

8. SECRETARIAT AND ADMINISTRATIVE ARRANGEMENTS OF THE CAG

- (1) The CAG should identify a SAAVI-supported trial site member of staff and a non-staff member of the CAG, preferably with good written and verbal communication skills, to function as a secretariat.
- (2) The secretariat will be responsible for the following:
 - (a) to provide administrative support for the proper functioning of the CAG in line with its Constitution and with the support of the trial site unit, including distribution of the agenda and minutes prior to the meeting of the CAG;
 - (b) to prepare documents, including clinical trial and other research protocols, for input from the CAG;
 - (c) to liaise with members of the CAG, PIs and SAAVI, including receiving communications from SAAVI;
 - (d) to compile reports on the activities of the CAG for SAAVI and, where appropriate, for the National CAG Forum; and,
 - (e) to arrange travel and accommodation for members of the CAG.

9. CAPACITY BUILDING AND DEVELOPMENT OF THE CAG MEMBERS

- (1) PIs, trial site staff, CAG members, and Masikhulisane will work together to educate and inform new and existing CAB members about all issues pertinent to the local CAG and HIV vaccine development.
- (2) Some CAG meetings will be educational in nature, ensure general capacity building, and must address the following: the background to HIV vaccines, science and research, HIV vaccine research and development, ethics, legal and human rights, protocol development and evaluation, and community involvement. Masikhulisane and the PI will support this learning process.
- (3) SAAVI will inform CAGs about workshops and conferences (local and abroad) of interest to the CAGs.
- (4) Masikhulisane and the PIs will make available relevant materials of interest to the CAGs.

10. SPECIFIC OUTREACH PROGRAMMES BY THE CAG

Each CAG and local trial site unit must design and implement outreach programmes to involve persons of all socio-economic status, men and women, and adolescents. In areas where adolescent CAGs exist,

the CAG must forge a supportive relationship with the adolescent CAG.

I 1. CONSULTATION WITH THE CAG

The PI or his/her delegate(s) must consult with the CAG on all matters affecting the conduct of clinical trials in each community, including but not limited to:

- (a) the preparation of applications for research, budgets and budget revisions; and,
- (b) choosing in which HIV vaccine research and HIV vaccine research-related protocols to participate.

I 2. CONSTITUTIONS OR TERMS OF REFERENCE OF THE CAG

Each CAG must develop and adopt a Constitution or terms of reference that is consistent with these Guidelines. This document must address issues such as regular elections, composition, membership, office bearers, roles and responsibilities, meetings, voting, conflict resolution and dissolution.

I 3. DISSOLUTION AT CLOSURE OF A TRIAL SITE

When a trial site unit closes down for any reason the CAG at that trial site must be dissolved.



HIV VACCINE INFO-LINE:

080 VACCINE
080 8222 463

www.saavi.org.za

SAAVI was established in 1999 as an initiative of the South African government with initial funding from Eskom, the Departments of Health and of Science and Technology. SAAVI is a lead programme of the South African Medical Research Council (MRC). It coordinates and supports the research, development and testing of HIV vaccines in South Africa with the aim to find a safe, affordable, effective and locally relevant HIV vaccine.

SAAVI funds the activities of investigators at a number of South African academic institutions. These activities have included: development of potential HIV vaccines; laboratory science; immunology; development and ongoing support of a South African clinical infrastructure; testing of HIV vaccines; biostatistics; ethical, socio-behavioural, human rights and legal research; and, community involvement in HIV vaccine research and development.

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