

Guidelines for Community Advisory Groups

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INTRODUCTION

Health research in South Africa can provide critically needed benefits for the health system and for the people of South Africa. The South African National Health Act (2003) mandates that all planned health research be reviewed and approved by Research Ethics Committees (REC's) prior to implementation with oversight of Research Ethics Committees provided by the National Health Research Ethics Council.

The Department of Health therefore recognises the importance of well-designed scientifically rigorous research that meets the highest ethical standards. Health research can therefore play a major role in helping to realise the rights of access to health care and to health as contained in our Constitution.

In many instances, community engagement may serve to increase the relevance and quality of proposed research, and its acceptance by affected communities. One way in which community engagement can occur is via Community Advisory Boards (CABs). CABs can provide a mechanism to harness the expertise of key stakeholders and offset potential power differentials that may exist between researchers and participating communities, amongst other functions. CABs are recognized as a key element of good participatory practice in trials (GPP, 2011) along with a range of other stakeholder advisory mechanisms.

It is necessary to develop some guidance to assist key stakeholders such as investigators, participating communities and Research Ethics Committees to develop and evaluate such mechanisms. These guidelines for the establishment of CABs are intended to promote the development of a mutually beneficial and meaningful partnership between health researchers and community stakeholders within a vibrant human rights environment.

1. DEFINITIONS

- 1) The term 'Community Advisory Board (CAB)' is intended to include the term 'Community Advisory Group (CAG)' and refers to CABs that are established for research with a particular target group (e.g. adolescents) or for the purpose of particular studies (e.g. TB vaccine studies) or for research more generally.
- 2) The term 'community' is complex, but is intended to refer to a group of people who have a common set of interests, share a common set of characteristics, or live in a common area. It is possible that individuals can be a part of multiple 'communities' at the same time (GPP, 2011). Applied to research, relevant communities include: individuals and groups that represent the interests of potential participants and the participating community, and others locally affected by the research, healthcare providers, non-governmental organisations, civil society groups, and community-based organisations (ibid).

2. RATIONALE FOR THE ESTABLISHMENT OF CABS

- 1) The engagement of participating community representatives and other stakeholders can assist to ensure the quality of proposed research, its relevance to the affected community, and its acceptance by the affected community.
- 2) Relevant considerations for the establishment of a CAB include:
 - (a) That the proposed research may hold distinct potential risks for participants and participating communities, such as stigma and discrimination;
 - (b) That the populations to be recruited for the proposed research may have pre-existing vulnerabilities that increase their susceptibility to research-related risks;
 - (c) That the proposed research may have a substantial impact on areas where it will be conducted;
 - (d) The proposed research is particularly complex or lengthy;
 - (e) That similar studies elsewhere have historically included CABs as an additional safeguard;
 - (f) That investigators may need to harness the expertise of community representatives in order to design and conduct the research more effectively; and
 - (g) That inequalities may exist between participating communities and investigators in terms of power, education and resources.

3. ROLES AND RESPONSIBILITIES OF THE CAB

- (1) CABs can contribute to the ethical and scientific quality, relevance and acceptability of the proposed research in a number of ways, including:
 - (a) By educating the research team on local cultural and community norms that may impact the research, including community entry, recruitment, informed consent and other processes;
 - (b) By educating the community on aspects of the research, including the purpose, and design of the research, as well as ethical-legal rights of participants;
 - (c) By advising the research team on key issues such as potential risks and burdens for participants or host communities that may be hidden from researchers, and how to minimize them, as well as potential benefits of the research for host communities and how these could be maximized. Other issues include appropriate recruitment, consent and payment for research participation;
 - (d) By making inputs into the research process, including as far as possible, protocol development and review, implementation of the research and results dissemination
 - (e) By advising the research team on the research agenda and ensuring a community voice in the research process; and
 - (f) By assisting to ensure that research conduct complies with human rights and ethical standards.
- (2) CABs may undertake a number of activities that inform the appropriate recruitment of potential participants. However, CABs should not directly recruit participants into research because the roles and responsibilities of recruiters are substantially different to those of CAB members and this may create conflicts of interest. For example, CAB members may be less likely to voice concerns about a study if they are responsible for recruiting participants to that same study.

4. ROLES AND RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH STAFF

- (1) Principal Investigators (PIs) of specific studies or organizational heads of research units are encouraged to anticipate the need for a CAB and to take steps as early as possible to initiate the establishment of a CAB, where necessary.
- (2) In areas where study-specific (e.g. TB vaccine studies) and population-specific CABs (e.g. an adolescent CAB) are formed, investigators should encourage networking and supportive relationships between these structures.
- (3) Consideration should be given by the PI to limiting the number of CABs per geographical research area by encouraging the evolution of a generic CAB dedicated to several research studies, except where good reason exists for establishing a separate CAB, such as the need for particular expertise to develop.
- (4) CABs may be dissolved when a study is completed however PIs should consider whether support should be given to the continued existence of a generic CAB.
- (5) PIs should undertake to build the capacity of CAB members, and these capacity-building activities should be appropriately funded.
- (6) PIs should also provide administrative support to the CAB (including but not limited to meeting costs, and access to communication methods) that enables them to undertake their core functions outlined in section 3.
- (7) PIs should share responsibility for administrative and capacity-building support where one CAB is operating in an area where studies are being conducted under different PIs, and ensure that, in such instances, resources are fairly shared.

5. JOINT RESPONSIBILITIES

- (1) Community representatives and PIs should set up the CAB jointly. This should 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 various sectors and stakeholders in a public meeting, taking into account the considerations listed below.
- (2) Representatives should be sought from groups and organisations who can influence or are affected by the conduct or outcome of the research. When electing the representatives, the following should be considered:
 - (a) Inclusion of representatives of populations likely to be recruited for the study (ies);
 - (b) Inclusion of representative(s) from the Community Development Forum and Clinic Health Committee(s), or other similar committees;
 - (c) Inclusion of traditional authority representatives where such authority exists;
 - (d) Inclusion of locally identified political and religious leadership in the community;
 - (e) Inclusion of representatives from Civil Society Organisations;
 - (f) Diversity in terms of gender, race and age;
 - (g) Inclusion of socially vulnerable or marginalised members of the community; and
 - (h) The possible inclusion of study participants.

6. ORGANISATIONAL STRUCTURE OF THE CAB

- (1) Each CAB should develop and adopt a Constitution, or terms of reference, that are consistent with these guidelines, and address issues such as composition, membership, office bearers, roles and responsibilities, meetings, voting, conflict resolution and dissolution.
- (2) The organisational structure of the CAB should be appropriate to the nature of the study conducted. In general, a CAB should:

- (a) Comprise a large enough membership to represent various sectors and interest groups, for example between 10 to 20 members;
- (b) Review membership of the CAB at regular intervals;
- (c) Select resource persons to serve on the CAB for a predetermined period or to attend CAB meetings, where specialist expertise is required in any area of interest to the CAB; and
- (d) Ensure that voting members of the CAB exclude PIs, study staff, resource persons, and *ad hoc* specialists.

7. SECRETARIAT AND ADMINISTRATIVE ARRANGEMENTS OF THE CAB

- (1) The CAB should develop meeting procedures:
 - (a) Meetings should be carefully planned and organized, for example, each CAB member should receive an agenda prior to each meeting;
 - (b) Meetings of the CAB should take place regularly and as required by the needs of the research process;
 - (c) Discussion and outcomes at CAB meetings should be recorded as minutes and approved at subsequent meetings as an agreed record of that meeting's discussion and decisions; and
 - (d) The CAB should maintain a handbook or file that consists of the CAB guidelines and any other relevant guidance documents available to all members and for use in meetings.
- (2) The secretariat should include a CAB member who is not a paid staff member of the research team or institution.
- (3) The secretariat should be responsible for the following:
 - (a) To provide administrative support for the proper functioning of the CAB in line with these guidelines and its Constitution, including writing and distribution of the agenda and minutes prior to the meeting of the CAB;
 - (b) To prepare documents for input from the CAB;
 - (c) To liaise with members of the CAB, PIs and other stakeholders;
 - (d) To compile reports on the activities of the CAB for relevant fora; and
 - (e) To arrange travel and accommodation for members of the CAB.

8. ROLES AND RESPONSIBILITIES OF RESEARCH ETHICS COMMITTEES

- (1) Even while PIs are primarily encouraged to anticipate the need for a CAB and to take steps to establish CABs, RECs should also consider whether there are instances where community engagement appears especially important and where the development of a CAB may add ethical protections.
- (2) In such instances, RECs should make recommendations to investigators in this regard.

9. CONCLUSIONS

The NHREC recommends that investigators attempt to engage the participating community and other stakeholders in a relationship of mutual respect and collaboration because such engagement may add to the quality and acceptability of research projects, particularly those that involve vulnerable communities in complex research endeavors. The establishment of a structure such as a CAB may assist to achieve this aim.

CONTRIBUTORS TO THE GUIDELINES

Community Advisory Boards

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Main Research Ethics Committee at University of Pretoria

REFERENCES

Although a number of guidelines and documents addressing the ethical aspects of clinical trials touch on standards of community involvement in research, few of them provide any detail on CABs as a mechanism for achieving them.

These generic guidelines have been developed by the National Department of Health Cluster responsible for Clinical Trials Management and the Masikhulisane SAAVI Community Involvement Programme of the South African AIDS Vaccine Initiative (SAAVI) at the Medical Research Council under the leadership of Prof A Mbewu.

The guidelines were also presented to the National Health Research Ethics Council which gave input and ratification.

The guidelines have relied on the SAAVI CAB guidelines of 1 July 2007 that were developed through a consultative process involving the Department of Health, SAAVI CAGs, the SAAVI National CAG Forum, and the SAAVI PIs.

The following HIV vaccine-specific guidelines were consulted in the preparation of the SAAVI guidelines:

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

Other Guidelines consulted are:

Joint United Nations Programme on HIV/AIDS (UNAIDS) *Good participatory practice guidelines for biomedical HIV prevention trials* Geneva: Joint United National Programme on HIV/AIDS (UNAIDS) 2011. on 10 March 2012 available at: http://data.unaids.org/pub/Manual/2007/jc1364_good_participatory_guidelines_en.pdf