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**The Representation of Community
Interests in AIDS Research**

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The representation of Community Interests in AIDS Research

Introduction

The representation of community interests in clinical AIDS research is still a novelty in Europe. The same is true of community advisory boards, which are one method of obtaining this representation.

Community representation is a means to involve people with HIV/AIDS and those communities threatened by the virus in the planning and implementation of trials. Individual interests or those of the group can enhance the quality of research as well as changing the role of the object of research into that of an accepted party and equally active partner.

Considering the interests of trial participants and of the communities to whom they belong (and who are supposed to benefit from the research) is a long-standing claim. However, in Europe (in contrast to the USA) until recently there have been few attempts to put this into practice.

Instead, there is no history of collaboration between communities and researchers, between people affected and the pharmaceutical industry. Communication hardly exists.

There is much to be done in this area, and maybe this is our chance:

- to achieve a mutual understanding of objectives and interests by means of communication and collaboration and to improve the planning and implementation of clinical trials, so as to do justice to all parties involved. Community advisory boards may be one instrument to accomplish this.

We are quite aware that much of what we describe below is idealized and does not depict the current situation in Europe. In fact, Community Advisory Boards are frequently not established until the planning of the trial has been concluded (which destroys one of the main possibilities of taking influence in the process), or they are refused actual participation or decision-making. To establish appropriate structures that make community participation possible will require the willingness to compromise and to listen to one another, and the first solutions may be less than optimal. With this in mind, some of the statements and regulations described below are an expression of a goal which is yet to be achieved. Our intention is to make the compromises and contradictions that determine the present situation of existing CABs transparent, not least because we want to encourage a discussion about the purpose of CABs and prevent community members from being discredited.

In our text we have generally referred to "decision making committees" for those committees responsible for essential decisions in clinical trials. In many trials, this will be the so-called steering committee. By "sponsor" we refer to the industrial partner who provides the investigational drug and who usually finances the entire trial, or at least part of it.

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1. Community representation in clinical trials is necessary and useful

"Few studies have more starkly posed the dilemmas in socially sensitive research than the recent and ongoing clinical trials of medications to treat AIDS. One response to such dilemmas is to include potential participants or surrogates for them in decision making. Although the investigator and relevant regulatory bodies are not absolved of responsibility by community consultation, such a procedure may help to create a partnership between the investigator and participants, consistent with ethical duties of respect for persons, beneficence, and fidelity. Community consultation also may dampen participants' anxiety and increase perceived justice of decisions about the research. Such a procedure has the potential to mitigate ethical problems in research involving a wide variety of socially sensitive topics and in randomized clinical trials of treatments for conditions other than AIDS." [4]

1.1 Community representation: The history of an idea

The concept of community consultation was first brought up in the 1970s in the context of the ethics of clinical trials. The basic idea was that individuals who show even the slightest degree of 'vulnerability' (e.g. those who feel really sick or wish to be treated) have a serious disadvantage when talking to researchers as part of the informed consent process. Such patients may, for example, feel stupid when they ask certain questions. They may fear to appear uncooperative and get caught up in a dependent relationship, or that their queries might appear as an offense against the physician's or investigator's clearly more sophisticated scientific knowledge, etc. [4].

"Too frequently, field researchers have seemed to observe their subject from the verandah or to adopt an air of noblesse oblige in which they assumed they were above the realities of the culture they were studying." [4]

On the basis of these considerations it seemed, at first, reasonable to let prospective or actual trial participants take part in the discussion process during the planning phase of a trial.

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Frequently, this turned out to be difficult if not impossible. 'Surrogates' of prospective trial participants were consequently included in the discussion process, i.e. people who fulfilled requirements of representing the study population. This concept was called 'community consultation'. The goal of such meetings was defined as follows:

"The goal of such a meeting is to learn whether the proposed research can be conducted in such a way that it will be approved by most members of the participant population. If a substantial number of prospective participants disapprove the plans for the study, it is reasonable to predict that it cannot be conducted successfully." [4]

Even then it became clear that this concept would not only affect ethical questions and responsibilities, but could as well contribute to the improvement of the quality of research:

"Involvement of the community of interest in the design of research and interpretation of results is likely to increase the richness of research questions, the validity of methods, the meaningfulness of interpretations, and the speed and scope of dissemination of results." [4]

The participation of community representatives in institutional review boards has also been recommended in the ethical guidelines [3] of the Council for International Organisations of Medical Science (CIOMS):

"Local Review committees should be so composed as to be able to provide a complete and adequate review of the research activities referred to them. They should include ... as well as lay persons qualified to represent the cultural and moral values of the community ... Committees that often review research directed at specific diseases or impairments, such as AIDS or paraplegia, should consider the advantages of including as members or consultants patients with such diseases or impairments." [3]

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Non-governmental organisations (NGOs) like the 'Deutsche AIDS-Hilfe' have also asked for community participation in AIDS-research:

".. adequate financial support for research projects and the right for community organisations to co-determine to whom they are allocated; - with respect to clinical trials, communities must have the right to be consulted on issues such as allocation of funds, approval, design, implementation and data analysis ..." ["Wahlprüfsteine 1994". Deutsche AIDS-Hilfe e.V., Berlin, 1994].

1.2 Arguments in favour of community representation

Some basic considerations illustrate that community consultation may not only serve the interests of trial participants, but also has the potential to increase the efficacy of clinical trials:

⇒ Respecting the needs and concerns of the communities affected has led to a dramatic increase in compliance with trial protocols. The reduction in the number of drop-outs from ongoing trials has had significant impact on the interpretation and evaluation of results. Reliability of clinical trial results has improved and general application of the results has been speeded. Better results have led to accelerated approval. Therefore, the varying interests of the different communities should be taken into account in the trial design.

⇒ Communication and collaboration on a day-to-day basis between the pharmaceutical industry and the investigators on the one hand and the affected populations on the other are still not common practice in medical research. Community representatives provide a good opportunity to breach the existing gaps and to help establish communication in the interest of all parties involved.

⇒ During the investigation and development of new HIV and AIDS treatments numerous

imponderables may occur for scientific or ethical reasons or due to the behaviour or system of values of the people involved. Each party involved (the pharmaceutical industry, the investigators, governments and the communities) has its own interest in the trial. It is impossible to deal with this diversity and to avoid problems that may arise from these differences, unless there is a willingness to consider the interests of all parties involved, to cooperate, and to make compromises.

⇒ However, the involvement of community representatives in clinical trials is much more than just a question of responsible and ethical behaviour: both the pharmaceutical industry and the investigators depend on the social groups involved, because they are the pool of potential cooperative trial participants. Therefore, the image and acceptability of a trial are essential to its success.

Investing in clinical trials can only be profitable if a sufficient number of volunteers can be recruited and their compliance guaranteed.

⇒ People with HIV/ AIDS often require access to treatments that are promising but not yet approved. In most European countries mechanisms to account for this need have yet to be developed. Most of the currently available compassionate use programs are still lacking adequate consideration and respect of critically ill patients. Accounting for the variety of individually administered treatment regimen could definitely bring a trial closer to current practice.

⇒ The involvement of community representatives in medical research does, of course, cause expense on behalf of the sponsor (which is sometimes used as a counter-argument). These costs are, however, minute in comparison with the total cost of a trial. Moreover, trial organisers should be willing to pay this minimal amount of extra money for community participation, thus contributing to the improvement of the quality of a trial and its acceptability.

In summary, there are a number of serious reasons for extending community involvement in clinical research. Individual pharmaceutical companies and some AIDS researchers now

show a much more positive attitude towards community participation than just a few years ago.

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1.3 Community representation in the US

In the US, community participation in almost all phases of clinical AIDS research is much more common than in Europe. The first community advisory boards in governmental institutions and pharmaceutical companies were established about five years ago. Governmental CABs have usually been set up as standing advisory committees and participate in all aspects of design and implementation of clinical trials. The best known governmental CAB is probably the Community Constituency Group (CCG) at the NIAID (National Institute of Allergy and Infectious Diseases at the National Institutes of Health) AIDS Clinical Trials Group (ACTG). Other important CABs in the USA are the Community Constituency Group and its CABs at the Terry Bein Community Programs for Clinical Research on AIDS (CPCRA) and the Community Representation at the AIDS Vaccine Evaluation Units (AVEU) of NIAID. Most major pharmaceutical companies involved in AIDS research in the US have also set up CABs. The first industrial CAB was that established at Burroughs Wellcome in 1990.

NIAID ACTG Community Constituency Group (CCG)

The NIAID ACTG took up its work in December, 1987. ACTG is a network of clinical trial sites participating in the evaluation of HIV treatments; at present, it consists of 58 AIDS Clinical Trials Units (ACTUs) at universities and medical centres in 21 US-federal states.

Community representatives have participated in the meetings since November, 1989 (the first ones were ACT UP activists who came uninvited), and in May, 1990, the Community Constituency Group was formed. Since the end of 1990, the CCG has officially been a part of the ACTG system and has been represented in the executive as well as in the scientific core committee. Today, each of the 58 ACTUs that form the ACTG is obliged to establish a local CAB.

"The purpose of the CAB is to foster interaction between ACTU staff and HIV infected individuals, health care providers and advocacy groups. It is hoped that, through the CAB, the staff will be better able to disseminate information about the ACTU and clinical trials, the availability of investigational therapies, and obtain input about study design and other factors that might impact accrual and/or compliance." [8]

At present, the CCG has a total of 30 members (24 in the ACTG for adults and 6 in the ACTG for paediatric trials) who are either people with HIV/AIDS or who represent the communities that are most affected. The CCG has 2 representatives in each of the other ACTG committees, including the executive committee.

A survey conducted at the end of 1992 among the CABs at the ACTG showed a number of shortcomings that impede the work of these groups. Among other things CAB members complained that the meetings were not held at regular intervals and were unsatisfactory, that principal investigators showed little interest in the CABs' work and made their decisions against the CABs' recommendations. They also felt that financial support was insufficient, that some communities were still underrepresented in the CABs, and that there was a lack of interest and an apathetic attitude on the part of the communities [7].

The shortcomings found in the survey led to the development of guidelines for the work of the CCG (ACTG-CCG Standard Operating Procedures [6]) and the CABs (Guidelines for Community Advisory Boards [9]). These guidelines regulate important issues such as rotation of membership (2 - 3 years), reimbursement of expenses by NIAID, voluntary unpaid collaboration, and rights and duties of the members. They also lay down the internal structure of the groups. The CAB guidelines stipulate, among other things, that any community affected by HIV should be

represented in the group, that each CAB should determine its own organisational structure and should receive financial support from the corresponding ACTU. They also lay down the issues about which principal investigators should consult the CAB. An accompanying poll (CAB Evaluation Tool) should help to implement the guidelines.

1.4 Community representation in France

Community advisory boards are probably the best way to ensure community participation in clinical trials. Experience in France has shown that there are other ways for community representatives to influence decision-making, especially during the most important planning phase. These may not seem as effective as the means of an ideal CAB, however, they demonstrate yet another way of community representation.

ANRS (AGENCE NATIONALE DE RECHERCHE SUR LE SIDA) and TRT-5, a network of patients' "advocates" from five different community-based AIDS organisations (ACT UP, ARCAT-Sida, Aides, VLS and Actions-Traitments) made an agreement with the objective of improving information to patients and the informed consent procedure in clinical trials. Before the final decisions are made, the study protocols are reviewed by the TRT-5. Comments and suggestions are passed on to the principal investigator. Five protocols were reviewed between July and December, 1993, and the majority of suggestions and recommendations made by the TRT-5 were subsequently adopted in the protocol. Similar teamwork agreements are now under negotiation with pharmaceutical companies conducting trials in France that are not part of the ANRS research. [1, 2]

2. Community representation - chances and limits

2.1 Who can represent a community?

One of the main objectives of community participation in clinical research is to ensure consideration of the interests of the populations concerned. This requires the participation of the broadest possible spectrum of representatives of these populations. In addition, in multinational trials each region should be represented.

A community representative should himself be a person with HIV/ AIDS or should be in close contact with populations concerned and be in their confidence. In order to make sure that communication with the communities is satisfactory, a community representative should, if possible, also be in contact with NGOs or other informal groups. Even though it is preferable to have a democratic procedure for election or delegation of community representatives, the lack of adequate mechanisms and structures (e.g. patient parliament) has resulted in different approaches. Currently members in European Community Advisory Boards are appointed through a peer group mechanisms based on the existing structures of community based organisations and interest groups.

2.2 A question of professional qualification?

The pharmaceutical industry often argues and communities are concerned that community representation is a question of professional qualification. This implies that community representatives in clinical trials are required to demonstrate complex medical knowledge and extensive expertise amounting to that of the researchers involved. Accordingly, community members are often concerned about not being up to the knowledge and jargon of the researchers, and refrain from collaborating in the trial for fear of being incompetent. Communication in trial boards is indeed often hampered by the use of cryptic medical phraseology. In this context lack of medico-professional qualification is, in fact, a specious argument used to prevent community participation in clinical research.

So what type of competence or qualification is

really required? It is definitely not important to be able to understand and assess each and every medical detail. What is much more important is the safeguarding of the interests of the community. And this is less a matter of medical competence, but more a question of knowledge about the communities concerned, about the situation and requirements of their members and the conditions under which they live.

The expertise that is necessary to represent the interests of a community in a clinical trial refers to the ability to represent the interest of that community from the point of view of its members. The competence needed to do this is one of the qualifications a community representative should have rather than being a medical expert. There are several members of each organ of community representation in any case, and the personal competence of each member is complemented by that of the others, so that the sum total will be a wealth of experience and knowledge.

Should there ever be any problem because of lack of competence in any field (which is only normal, because it is impossible for anyone to be an expert in community interests, medicine, ethics, etc. at the same time), there is always the possibility of consulting external experts.

2.3 How can community representation be justified?

A community representative should be a member of the community he represents. However, community representatives are not bound by instructions from any particular group or organisation, but rather act as individuals on their own responsibility. Their presence and activities are justified by the confidence the community places in them. This requires transparency and frankness: it is important that decision-making processes and the flow of information involved in community participation be made transparent for the community, although this may be limited by the duty not to disclose any information classified as confidential. Nevertheless, transparency should help to clarify conflicts and to explain compromises that may arise, as in the field of tension between industrial, scientific, and community interests, optimum solutions from the community point of view may not always be possible.

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2.4 Community representation - weak and powerless?

It is just that field of tension mentioned above that calls for active participation, even if the position of community representatives may seem weak. However, they have access to information about the trial and the possibility of passing it on to the populations involved and to the general public. In addition, they can act as 'advocates' of the communities and pass on their statements and concerns to the parties involved in the planning of a trial. This may influence the acceptability and, as a consequence, the success of the trial. Thus it becomes possible to safeguard community interests and, at a later state, those of the trial participants.

The increasing number of clinical trials on HIV/AIDS treatments conducted in Europe strengthens the position of community representatives. These trials only become possible if people with HIV are willing to participate, i.e. to 'test' experimental treatments in a controlled manner. Their motivation also depends on the reputation of a trial and of the clinic where it is conducted, as well as on that of the manufacturer of the compound under investigation. Prospective trial participants often belong to social groups to which pharmaceutical companies and even investigators usually have no access and therefore do not know which queries and interests people have and which are the most important issues being discussed. Community representatives, on the other hand, have much better access and know more about the situation and the living conditions of HIV-positive people in the population group they represent than any investigator, politician, or pharmaceutical company. This puts community representatives in a powerful position: the reputation and acceptability of a trial are essential to its implementation and success. If a trial has a negative image among potential volunteers (e.g. due to lapses of the investigators or the sponsor, or maybe even due to insufficient information spread by

community representatives), acceptability will decrease dramatically. This will have a significant influence on people's willingness to participate in the trial and will result in problems with enrollment and compliance. Therefore, communication between organisers and communities is directly in the interest of a successful outcome of a trial.

Opposition to community representation may be a result of the varying interests and concerns of the parties involved. These are compared in the diagram in annex I.

2.5 Community representation - rules of the game

Community representatives often find themselves in a field of tension resulting from mostly varying, sometimes opposing interests and, occasionally, from the resistance of other parties or individuals involved. Moreover, unlike their US American colleagues, European community representatives (but also investigators and pharmaceutical companies) lack experience in other areas and thus have to develop the whole concept from the first step.

However, ACTG-CABs also have to overcome a number of difficulties, as demonstrated in the survey described above (see 1.3). But experience in the US has shown that regulations for CAB activities may at least help to formulate minimum standards and claims and to define procedures for cooperation with investigators and sponsors.

Exemplary regulations for a CAB (based on a generalized version of the regulations of the Community Advisory Board at the Multicentre European HIV Vaccine Trial Goebel) are included in annex II. They may not be easily applicable to any CAB, but they contain quite a few questions and aspects that should always be clarified and laid down in regulations, as they facilitate the CABs' work and help to make it more efficient.

3. Responsibilities of community representatives in clinical AIDS research

3.1 Community representation in clinical trials

While there are different mechanisms of community participation in clinical research, community advisory boards have become being the most common one.

One often heard reservation against CABs is that they do not really influence the course of events of a clinical trial but merely serve to legitimize decisions after they have been taken ("...at least the decisions have been taken after community consultation"). In the case of company CABs set up for a particular trial, there may be reasons for this reservation. These CABs are always at risk of acting on behalf of the company and trying to convince participants of the inevitability of certain decisions instead of taking the view of the community.

One way of responding to this danger and supporting the independence of community representatives is through a neutral organisation or body that protects community interests in clinical trials without being integrated into the trial structure or that of the sponsor. On the European level, the European AIDS Treatment Group (EATG) is one approach towards a supra-national representation of interest.

3.1.1 When should community participation start?

Mechanisms and bodies of community representation should be established before the trial is started and should influence the entire planning. In principle, it is also possible to start activities at a later stage when the planning is concluded, but this should be carefully considered as it would not be sufficient to be used only for cosmetic purposes to brush up the reputation of a trial after it has failed for one reason or another.

3.1.2 Trial design

The question of how a trial should be designed

in order to serve the interests and goals of both the companies/ researchers and the communities concerned can not be discussed in detail in this document (see also [10]).

However, even in the phase of planning and drafting of a trial several aspects should be taken into account that might become relevant in the actual trial phase and therefore have an influence on the work of the CABs. The following issues and questions should be considered in the protocol:

- ⇨ clear and complete information (including informed consent procedures) for the volunteers before the trial is started
- ⇨ information for the trial participants at regular intervals about provisional trial results (e.g. side effects, endpoints, etc.)
- ⇨ information for the participants about possibilities of access to the study drug after the trial has been concluded
- ⇨ information for the participants about the results at the end of the trial (including personal data; unblinding)
- ⇨ events that lead to the interruption of the trial
- ⇨ Are the duties and tasks of the participants appropriate?
- ⇨ Are the financial needs of the participants accommodated (e.g. trial insurance)?
- ⇨ information for the participants about the presence of community representatives, their tasks, how to get in touch with them

3.1.3 The trial phase

Once the trial is ongoing, community representatives have the task to check whether the general conditions and demands agreed on in the planning phase are met. In addition, they should, of course,

- ⇨ speak on behalf of the participants
- ⇨ scrutinize the provisional results (side effects, end points, etc.)
- ⇨ make sure that the participants receive full and accurate information.

3.1.4 Publication

When provisional or final trial results are being published, community representatives should try to ensure that

- ⇨ the participants are informed about the

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results

- ⇨ the results are published in a comprehensible manner and made available to the communities concerned.

Critical statements and an assessment of the trial results by community representatives should always be an option and should be considered when it comes to disseminating the results among the participants and the communities.

3.2 Community representation outside clinical trials

The safeguarding of community interests in AIDS research should not be limited to community representation in clinical trials. There are other levels of decision making which should not be neglected:

- Pharmaceutical companies,
 - governmental institutions and political lobbies,
 - hospitals, general practitioners and the corresponding institutions
- are more or less constantly making important decisions which determine further research and which are not necessarily associated with clinical trials. Standing CABs may be one possible way of ensuring community participation in these bodies.

3.2.1 Pharmaceutical companies

The manufacturer makes decisions about a number of questions long before a substance enters the phase of clinical investigation, for instance:

- ⇨ which treatment strategies or substances should be given priority and deserve further investigation?
- ⇨ which substances should enter the clinical trial phase, when should the trial start and how many volunteers are necessary?

In recognition of the necessity of community

participation on this level of decision making, community advisory boards have sporadically been established at pharmaceutical companies in Europe, e.g. the 'HIV Clinical Trials Advisory Board' at Burroughs Wellcome.

3.2.2 Governmental institutions

National institutions such as drug approval agencies or departments of research as well as international institutions (e.g. EU commissions, EMEA, etc.) play an important role in AIDS research and decide on issues such as:

- ⇨ which treatment strategies, substances or substance groups should receive support from national research funds
- ⇨ which substances should be approved for which conditions, on account of which results, how fast?

In general, the opportunities for community representatives to influence such decisions are still very limited in Europe (see 1.4; TRT-5).

3.2.3 Hospitals, General Practitioners, etc.

More decisions that require community participation are taken on the local or regional level, i.e. by the responsible persons at the institutions that serve as trial sites, and also by the local review boards. The following issues are, among others, relevant at the local level:

- ⇨ which trials should the institution participate in? To what extent?
- ⇨ how many details should information to patients contain?
- ⇨ which steps should the enrollment procedure consist of? (How can the volunteer's freedom of choice be guaranteed in view of the strained relationship between physician and patient?)
- ⇨ how should participants who wish to drop out or fail to follow the trial regimen be dealt with?
- ⇨ should the trial participants be kept informed about provisional results of the trial?

In the USA, local community advisory boards (e.g. at ACTG trial sites), have already become an integral part of the research system. However, they are still rather an exception in Europe.

"Institutions that regularly conduct clinical trials of therapies for HIV infection should have standing community advisory boards." [10]

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ANNEX I

Interests and worries of parties involved in clinical trials

Interests	Worries
<p>Pharmaceutical companies</p> <ul style="list-style-type: none"> • understanding opinions and interests of the communities • being aware of factors that might harm the image • cultivating a positive image among the communities • improving and accelerating accrual and compliance • optimizing publicity and outreach (creating expectations, exciting interest, having advertising appeal) • making sure that the company's behaviour is perceived as ethically and socially responsible (image cultivation) • 'justifying' the trial before third parties (e.g. the communities, NGOs, media) 	<ul style="list-style-type: none"> • losing their independence with respect to decision-making • disclosing economic reasons for certain decisions (especially if they are presented otherwise, e.g. as lack of productive capacity, etc.) • releasing confidential information to third parties (e.g. competitors) • having to deal with social groups with whom they would normally not wish to be in contact (e.g. gay men, drug users) • having to cover additional expenses
<p>Investigator</p> <ul style="list-style-type: none"> • having closer contact with the community than he would have as a physician; more credibility and better access • passing on the information about trials and experimental drugs to the community • improving patient enrollment and compliance • making himself understood by the community (researchers often speak a language that is incomprehensible to lay people) 	<ul style="list-style-type: none"> • having to deal with well-informed, sophisticated, self-conscious patients who might threaten the classic physician's role • seeing the scope of their scientific activities restricted • releasing (too much) information to the public during the planning phase
<p>Communities and their representatives</p> <ul style="list-style-type: none"> • being able to influence the structure and course of a trial • obtaining information • establishing communication with investigators and sponsors • protecting the interest of trial participants (in ongoing trials) • making publicity efforts and informing the public well • distinguishing themselves • informing the communities and helping to shape their opinion 	<ul style="list-style-type: none"> • being used or abused (e.g. as a marketing instrument) • deciding as a delegate without being one (fear of lack of legitimacy) • being responsible for decisions without being fully aware of what they imply (fear of not being competent) • coming into conflicts of interests and loyalty • being personally discredited (e.g. as being too close to the pharmaceutical industry)

Annex II:

Rules of the Community Advisory Board

1. Tasks and Goals

1.1. A community advisory board serves the purpose of formulating and safeguarding the interests of a particular community before the sponsors of a clinical trial and the physicians who participate as investigators. It is composed of independent representatives of the communities involved in the trial.

1.2 Main responsibilities of a CAB are:

- establishing and maintaining a flow of information between the communities involved and the trial organisers
- informing trial participants and advocating their interests
- passing on important information in a comprehensible manner
- being the point of contact for the trial participants
- being the point of contact for the communities, and
- advising the decision-makers and the central sponsor on issues such as accrual and compliance.

1.3 The decision-making committee will consult the CAB and discuss its opinion on all issues concerning the trial design, provisional analyses, end points, the drawing up of the study protocol (especially of informed consent procedures) and of its modifications, if necessary.

At the request of the CAB, the CAB's necessities and interests, as formulated by the CAB, will be discussed at the meetings of the decision-making committee.

1.4 The CAB will have access to the relevant information during the decision-making process as well as the right to comment on the issues in question before decisions are made. The CAB will participate in the decision-making process.

1.5 The CAB will be established prior to the planning phase of a trial in order to be able to perform its task well. The sponsor will be responsible for the initiation of this process.

2. Structure of community advisory boards

2.1 In order to avoid a conflict of interests, CAB members will not actively participate in the trial, neither as patients nor as investigators, nor will they work for the sponsor.

2.2 Collaboration with the CAB is voluntary.

2.3 CAB members will be nominated according to the following principles:

- Any group or region/ country involved in the trial will be represented in the CAB.
- If possible, CAB members will be nominated by corresponding NGOs (on a regional level) and, if it is a European trial, by Service Organisations such as EuroCASO, EATG, European Hemophiliac Association, etc.
- The decision-making committee and the sponsors are not entitled to make nominations.

2.4 CAB members do not participate as delegates of a particular organisation or community, but represent the views of the communities as individuals. Therefore, CAB members will let the

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communities know about their participation in the CAB and will make their work and decisions transparent and understandable.

3. Organisation

3.1 To perform its task, the CAB will hold periodical meetings (at least twice a year) with the decision-making committee as well as with the central sponsor. In addition, the CAB will hold periodic internal meetings.

3.2 The CAB established for a particular trial will coordinate its activities with the company CAB as well as with the CAB responsible for the region (if there is any).

3.3 The CAB will elect a chairman who has the following responsibilities:

- to convene and head internal CAB meetings
- to establish contact between all parties involved in the trial, especially between the CAB and the decision-making committee and the main sponsor.

3.4 The CAB will meet upon being convened by the chairman or at the request of at least 50 % of its members. Resolutions require a quorum of at least 50 % of the members.

Decisions will be taken by a simple majority. In case of parity, the chairman will have the casting vote. Minority votes will be permitted. They must be documented and presented by the chairman.

3.5 The CAB will inform the decision-making committee about its work. The CAB will send a representative to the decision-making committee, who will be a full (voting) member.

3.6 The CAB will decide on successors for members who have resigned and on the admission of additional members by the proposal of regional NGOs.

3.7 The responsibility to solve language problems as may occur in multinational trials will lie with the sponsor.

4. Information and communication

4.1 Periodically, the CAB will be informed of the progress of the trial as well as of all provisional or final results. This information will include:

- observations of adverse effects
- data and results obtained by the Center for Data Analysis
- modifications of the protocol (before they are made) and according proposals
- information that leads to the unblinding of the trial
- information on enrolment, inclusion, and compliance of participants
- publicity material and publications on the trial
- recommendations of the oversight committee
- recommendations of the scientific advisory committee.

Special events such as serious adverse effects or events that result in modifications of the protocol will require the immediate notification of all CAB members.

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4.2 CAB members will have the duty not to disclose any facts to outsiders. This duty will be specified in a separate confidentiality agreement.

4.3 The sponsor will have the duty to provide the CAB with the latest scientific information on the trial drug and related issues as published in relevant journals (e.g. by providing literature reviews, articles, etc.).

In addition, the CAB will have the right to obtain information independently, and to consult scientists.

4.4 The 'informed consent' paper will contain a reference to the CAB, its members and their tasks, so that trial participants have the possibility of contacting individual CAB members directly. Should this for any reason be impossible (e.g. if the setting up of the CAB is delayed), the sponsor will have the duty to inform the investigator in writing about the CAB members and their tasks and to ask him to forward this information to the trial participants.

5. Expenses

All expenses incurring from the CABs work will be reimbursed by the central sponsor. This includes travelling expenses, expenses for communication, consultation and information, as well as for translation services, if required.

.....
Chair decision-making committee

.....
Chair Community Advisory Board

.....
Sponsor

[Editorial note: This set of rules is adjusted for a situation where community representation in the steering committee or other trial boards is excluded as an option. Experience with the Multicentre European HIV-Vaccine Trial Goebel, sponsored by Immuno Vienna, strongly indicates a need to effectively establish community representation in the steering committee as well as the scientific advisory committee of a trial. The chairperson of the CAB should be directly involved in all other board or committee meetings. Any exclusion from communication or perceived discrimination against lay members will necessarily further reduce the credibility of the established mechanism of community representation. Once established, community representation should be given any support possibly available to improve the credibility of the individuals in a CAB when addressing their communities. This may also include an authorized independently administered budget for communication and publication.]

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