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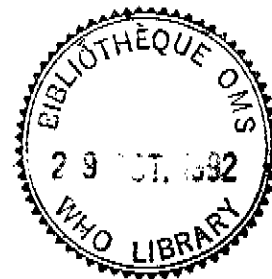
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GLOBAL  
PROGRAMME  
ON  
**AIDS**

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REPORT OF THE INFORMAL CONSULTATION  
ON GUIDING PRINCIPLES FOR  
THE CONDUCT OF INTERNATIONAL  
COLLABORATIVE AIDS RESEARCH

GENEVA  
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WORLD  
HEALTH  
ORGANIZATION

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## 1. Introduction

The global nature of AIDS has generated extensive collaborative biomedical, behavioural and operational research that has involved funding agencies, pharmaceutical companies, and university and governmental scientists from industrialized and developing countries. The need for collaborative multidisciplinary research will intensify as ways are sought, through behavioural studies, to modify high-risk behaviour, and as potential anti-HIV vaccines, immunodiagnostic tests, antivirals, immunomodulators, and other drugs for opportunistic infections and sexually transmitted diseases are developed.

A recent review of AIDS-related research in sub-Saharan Africa identified 559 AIDS-related research projects in 35 countries. Of these, 53% were collaborative and involved 87 external groups; initially only about half of the studies were known to national AIDS control committees, making it highly unlikely that the results would be rapidly utilized in local prevention or control programmes.

Although many AIDS-related research activities have been collaborative in the true sense, others have been directed solely by the sponsoring country or agency, with little or no input from local investigators. All too frequently, foreign scientists have used local contacts to gain access to a population group and obtain samples for analysis in laboratories in their home countries, never making the results available to their hosts. These episodes have been very discouraging to local investigators, who have felt exploited.

There are currently no published principles to guide institutions, funding agencies, and scientists from industrialized and developing countries in preparing collaborative research projects. In order to prepare a set of guiding principles applicable to AIDS-related research, an informal consultation was convened in Geneva by the World Health Organization (WHO) Global Programme on AIDS (GPA) from 1 to 2 February 1990. Among the participants were representatives from funding agencies, and scientists from developing and industrialized countries (see Annex). The consultation was chaired by Dr F. Marc LaForce.

The following general topics were discussed:

- the problems and expectations of sponsoring agencies and collaborating scientists;
- the key elements for successful scientific collaboration;
- the relative merits of institution-based and investigator-based collaboration, and the specific characteristics of a research institution that favour successful collaboration; and
- the means of promoting good practice in international collaborative AIDS research.

Brief introductions to each of the topics were given by a representative of a funding agency and by a scientist from a developing and an industrialized country.

## **2. Problems and expectations of sponsoring agencies and collaborating scientists**

The most common problems faced by funding agencies and their main expectations are as follows.

### Problems faced by funding agencies:

- insufficient funds for planning;
- competition between funding agencies;
- lack of coordination between government agencies;
- lack of standard international ethical guidelines;
- governmental bureaucracy;
- lack of access to current scientific information in the host country;
- overexpectations of the time local personnel can give;
- identification of potential collaborating scientists and institutions in developing countries.

### Expectations of funding agencies:

- clear definition of country priorities;
- adequate reporting and accounting systems for projects;
- national and local review of research projects;
- continuity of key personnel;
- need to strengthen institutions.

There was universal agreement that insufficient funds are set aside for planning. Many of the difficulties encountered in research projects could be avoided if on-site meetings were held prior to the submission of research proposals. Such meetings would allow for discussion of protocol design and provide the setting for an accurate inventory of local capabilities. Several participants felt that money spent on preliminary meetings was an excellent investment and was likely to be cost-effective over the length of a project.

The representatives of funding agencies acknowledged that there is poor coordination of research activities between agencies, which has sometimes resulted in duplicative and competitive awards. They felt it inappropriate for one agency to assume overall coordinative function and suggested that WHO was ideally positioned to provide leadership in this area. They agreed that there was a need for ethical guidelines for international research, and welcomed the joint initiative planned by WHO and the Council for International Organizations of Medical Sciences (CIOMS) to update the CIOMS guidelines published in

1982, which address ethical issues in basic, clinical, behavioural, and epidemiological research<sup>1</sup>. Further, they felt that it was essential that a formal review should be undertaken at the country level to ensure that proposed sponsored research is consistent with country priorities. Lastly, they underscored the problems arising from governmental and institutional bureaucracy and the frequent turnover of key personnel, which delay the start and, at times, the completion of projects.

The problems and expectations of collaborating scientists are summarized below.

Issues of greater importance to scientists in host countries:

- collaborating investigators not properly trained for field work;
- lack of funds for planning;
- lack of access to scientific data from research studies worldwide;
- poor local facilities for laboratory research;
- lack of involvement in design of protocol;
- local competition among investigators;
- expectations for publication and presentation of results;
- discrepancies in reimbursement for collaborating in research projects;
- government bureaucracy.

Issues of greater importance to scientists from industrialized countries:

- lack of funds for planning;
- confusion about governmental and institutional roles in projects;
- government bureaucracy;
- lack of on-site trained staff;
- lack of appropriate on-site laboratory facilities;
- lack of access to the results of projects.

The participants stressed the need for all the scientists collaborating on a particular project to participate in protocol design, be involved in data analysis and interpretation, and have free access to all the data generated. There was extensive discussion as to who should have control over or have legal ownership of clinical specimens. It was pointed out that in some countries, for example, the Netherlands and the Federal Republic of Germany, legislation gives ownership of serum specimens to the individuals who donated the samples. However, such a policy is not widespread, and frequently ownership is a function of where samples can be stored most safely. Nonetheless, there was general consensus that ownership should rest with the country from which samples are taken and that future studies using previously collected clinical specimens should be discussed with the original investigators who helped to collect them. Scientists from developing countries emphasized that the large discrepancies in personal and professional resources available to scientists working in

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<sup>1</sup> Proposed international guidelines for biomedical research involving human subjects, Geneva, Council for International Organizations of Medical Sciences/World Health Organization, 1982.

industrialized and developing countries caused problems and that salary supplementation for local investigators was necessary. Differences in the academic pressures on collaborating scientists were also a concern.

### **3. Key elements of effective collaboration**

The general characteristics that define projects with effective collaboration between scientists from different countries are summarized below. All the participants agreed that an atmosphere of partnership, equality, trust and sensitivity is essential and that this can only develop if there is continuity of personnel. They also underscored the need for a clear understanding of mutual expectations and the involvement of all investigators in all phases of the project.

#### Characteristics of effective collaboration:

- expectations understood by all participants;
- continuity of personnel;
- atmosphere of partnership, with equality, respect, trust and sensitivity;
- formal protocol review by all parties;
- mutually beneficial project;
- national commitment in host country;
- sufficient finances;
- involvement of all participants in all phases from inception through implementation, analysis and presentation of results;
- transfer of technology;
- exchange programmes for researchers;
- training opportunities for young investigators.

### **4. Relative merits of institution-based and investigator-based collaboration**

Participants highlighted the difficult choice that sometimes has to be made between direct investigator-based support, which is more likely to achieve quick, short-term success, and the slower process of working with institutions, which provides important opportunities for strengthening local research capabilities. Although it is individual investigators rather than institutions who do research, it was generally agreed that investigators should be affiliated to recognized institutions such as ministries or universities, except under very special circumstances. It was conceded that, while institution-based research is more cumbersome, since further bureaucracy is involved, the rewards of networking and strengthening of institutions outweigh the disadvantages. The WHO Special Programme for Research and

Training in Tropical Diseases and Special Programme of Research, Development and Research Training in Human Reproduction were cited as two examples of successful long-term support of medical institutions that has resulted in the development of well-trained cadres of independent investigators.

All institutions involved in collaborative research activities should receive funds for non-research expenses directly associated with a research project. Adequate reimbursement for the additional costs incurred by hosting a large externally-funded research project could serve as a stimulus to encourage broader participation in collaborative research and to improve the quality of the research proposals submitted.

#### **5. Means of promoting good research practices**

Four presentations addressed the question of how to promote good research practices. The importance of a rigorous review process to guarantee the highest standards of research was stressed. It was emphasized that it was essential for investigators to remain sensitive to local priorities and needs. There was a need for a balanced research agenda that not only focused on biomedical research but also acknowledged the importance of socially oriented research. It was felt that many of the problems that have plagued some research projects might well have been prevented by a realistic inventory of personnel and equipment before the development of the research protocol. The role of institutions in promoting good practices was highlighted, as was the importance of adhering to the principle that research projects should be consistent with national guidelines. Ethical issues needed clarification and that, in the final analysis, research collaboration that was characterized by sensitivity and equality had the best chance of success. It was emphasized that institutions had specific responsibilities, such as the development of review and coordinating boards and codes of conduct for scientists working on AIDS-related research. The need for more formal and informal interaction between scientists involved in AIDS-related research was also underlined.

#### **6. Guiding principles for the conduct of international collaborative AIDS research**

On the basis of its discussions, the consultation recommended the following guiding principles.

- (a) All research proposals should be consistent with national priorities, undergo review at national and institutional levels, and be coordinated nationally.
- (b) All collaborating scientists should participate in the development of research projects.

- (c) To facilitate the development of high-quality research proposals, funding agencies should set aside monies specifically aimed at project development. These funds would encourage on-site meetings between potential collaborating scientists before proposals are submitted which would help to ensure that proposals are developed collaboratively, that existing resources are inventoried, and that the expectations of both investigators and institutions are clearly understood.
- (d) Funding agencies and collaborating scientists from industrialized countries should recognize the obligation to strengthen research capabilities in the host country by encouraging appropriate technology transfer and training.
- (e) Funding agencies should recognize that appropriate overhead expenses are legitimate costs incurred by all collaborating institutions and that provision of these funds over time will result in the strengthening of institutions.
- (f) In the interests of transfer of technology, all aspects of studies, including laboratory investigations, should be carried out, whenever possible, in the host country.
- (g) All collaborating scientists should be affiliated to a recognized institution, such as a university, ministry, research institute, pharmaceutical company or duly constituted nongovernmental organization, and support for individuals working independently should be provided only under exceptional circumstances.
- (h) All countries should develop codes of conduct for investigators working on AIDS-related projects, and investigators should strictly adhere to the relevant codes.
- (i) All collaborating scientists must have a clear understanding of responsibilities and expectations. An exchange of letters between researchers detailing responsibilities for laboratory and field work, data analysis, preparation and authorship of manuscripts, and presentation of results at international meetings is strongly advised.
- (j) All collaborating scientists should have complete and equal access to scientific data generated by research studies and should participate in the data analysis.

**7. Recommendations to WHO**

The consultation made the following recommendations as to the role of WHO in ensuring effective collaborative research.

1. WHO should assume responsibility for facilitating and supporting coordination between funding agencies.
2. WHO/GPA should serve as a resource for researchers who wish to identify potential collaborating scientists in industrialized or developing countries.
3. WHO/CIOMS should prepare and circulate guidelines on ethical issues in epidemiological, behavioural, clinical, and basic research that can be applied to AIDS-related research.

## Annex

### List of Participants

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Dr Jonathan Gold, Director, Special Microbiology Lab, Memorial Sloan-Kettering Cancer Center, New York, United States of America.

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