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ESTABLISHMENT OF THE PAN AMERICAN INSTITUTE OF BIOETHICS IN CHILE

The Director of the Pan American Sanitary Bureau is pleased to report to the 20th Meeting of the Subcommittee on Planning and Programming regarding the establishment of the Pan American Institute of Bioethics (*BioEthics*).

Bioethics has emerged as a new applied field of study and research that is of universal interest and concern. Its influence is considerable in the scientific and technological community, in the sociocultural sphere, and in the political arena. In the countries of Latin America and the Caribbean, discussion of bioethics is limited. Most of the progress in this field and the solutions formulated to resolve bioethical problems come from countries outside these subregions. There has been a lack of pluralistic and objective dialogue that could facilitate frank and open discussion, and the generation of ideas. Moreover, reflection on both bioethical issues and proposed solutions, however pertinent, takes place in a framework of scarce resources.

As the 20th century draws to a close, bioethics has become a matter of crucial importance for the biomedical and social sciences and for health care. It constitutes the ethics of life in action and is a fundamental dimension of the biomedical humanities. Bioethics subjects the biological sciences, medical technology, health care, and the doctor-patient relationship to constant questioning and scrutiny.

During the 109th Meeting of the Executive Committee of the Directing Council of the Pan American Health Organization (PAHO), and Working Party of the Regional Committee of the World Health Organization (WHO), the Director reported to the Member Countries and Observers on the discussions that had taken place with the Rector of the University of Chile, Dr. Jaime Lavados, in regard to the relationship between scientific and technological progress and the growing importance of bioethics.

The Executive Committee shared the Director's concern for the vital ethical issues confronting society today. The Organization cannot disregard issues so closely related to its mission: health and well-being with equity for the peoples of its Member Countries. Accordingly, the Executive Committee asked the Director to draft a proposal, together with the University of Chile and the Government of Chile, and to submit it to the Subcommittee on Planning and Programming. The Office of Legal Affairs was entrusted with the responsibility of drawing up the proposal, taking into account its contributions to this field in recent years.

During the 19th Meeting of the Subcommittee, the discussion focused on the contribution of PAHO/WHO, the need to arrange for an evaluation after 10 years, and the importance of indicating in greater detail the activities to be carried out by the Institute. The original proposal document has been redrafted to reflect the Subcommittee's comments. The proposed agreement to be signed by the Government of Chile, the University of Chile, and PAHO/WHO has likewise been redrafted with respect to the financial contribution of PAHO/WHO and the evaluation.

Negotiations have been carried out with the appropriate authorities in Chile. Professor James Drane, of Edinboro University in Pennsylvania, resident ethicist at PAHO/WHO in 1990, made a valuable contribution. The Director is grateful for the support of the Kennedy Institute of Ethics at Georgetown University and the National Library of Medicine of the National Institutes of Health of the United States of America. He also wishes to express his profound gratitude to the members of the Advisory Group on Bioethics, which was convened in October 1992 to analyze and comment on the proposal.

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APPENDIXES

- A.** Support and commitment of the Government of Chile for and to *BioEthics*

- B.** Draft agreement for the establishment of *BioEthics*

- C.** Subject classification of the National Reference Center for Bioethics Literature of the Kennedy Institute of Ethics at Georgetown University

- D.** International regulation of research on human subjects

- E.** Members of the Advisory Group on Bioethics (20 October 1992)

PAN AMERICAN INSTITUTE OF BIOETHICS (*BioEthics*)

Program conducted by PAHO/WHO, in association with the University of Chile, for the purpose of studying the interaction between the biological sciences and the humanities, with emphasis on the ethical, social, and legal issues related to clinical practice and public health

I. THE CHALLENGE OF BIOETHICS

1. Initiative of PAHO/WHO and the University of Chile

The growing world concern about bioethical issues, the rapid and solid progress of bioethics in the developed countries, and the emergence of national and international organizations in this field make it imperative to provide for a systematic approach to bioethics in Latin America and the Caribbean. The lack of resources and opportunities for fostering dialogue, surveys, research, and the exchange of information in bioethics will require a concerted effort to promote and develop this field for the benefit of all countries.

In April 1992, the idea of a joint effort by PAHO/WHO and the University of Chile for the development of bioethics materialized in the initiative of the Director of PAHO, Dr. Carlyle Guerra de Macedo, and the Rector of the University of Chile, Dr. Jaime Lavados Montes, to create an institution, to be managed by PAHO and closely associated with the University, in order to meet regional needs.

The Government of Chile expressed an immediate and concrete interest, proposing that Chile serve as host country for the Pan American Institute of Bioethics (Appendix A). The University will contribute academic sponsorship for teaching and research activities and logistic support in the form of physical plant and personnel. A high-level Committee on Bioethics has been created in order to coordinate and furnish the support required for the success of the initiative. The Ministry of Health of Chile will lend institutional and personnel support. In order to formalize the creation and operation of the Institute, an agreement will be signed by the Government of Chile, the University of Chile, and PAHO/WHO, once the initiative has been approved by the PAHO/WHO Governing Bodies. (Appendix B).

The commitment of the Government of Chile and the University of Chile was reiterated by the Chilean delegation at the XXXVI Meeting of the Directing Council and at the 19th Meeting of the Subcommittee on Planning and Programming.

2. The Bioethics Revolution

The International Association of Bioethics defines bioethics as the study of the ethical, social, and legal issues that arise in health care and the biological sciences (1992).

Bioethics is a multidisciplinary field, not an isolated discipline, which has evolved over the last thirty years. It came into being as a response to the challenges that the extraordinary progress in the biological sciences posed to society's systems of values and beliefs. Although it arose initially as an area of knowledge concerned with ethical problems associated with clinical and scientific medicine, it rapidly expanded to include social and economic issues, in particular the planning and delivery of health care, the allocation of resources, animal welfare, and environmental concerns. Moreover, it incorporates various related disciplines or professions which do not, on their own, possess the resources necessary to deal with the political, economic, social, biomedical, and legal dilemmas encompassed by bioethics.

Bioethics has emerged as a new paradigm which brings together the concerns of our times. It aspires to establish a universal dialogue amidst the great diversity of concerns identified as "bioethical." The broad range of issues encompassed by the field of bioethics is revealed by the subject classification of the National Reference Center for Bioethics Literature of the Kennedy Institute of Ethics at Georgetown University (Appendix C). The growing number of international organizations addressing the issue of research on human subjects is another indicator of the fundamental importance of bioethics (Appendix D).

Bioethics constitutes in itself a generalized cultural phenomenon which synthesizes the progress of biomedical technology and the serious ethical conflicts generated. The application of new knowledge and techniques is a given in the modern world as the population searches diligently for good health and physical well-being. However, when issues arising from experimentation on and treatment of human beings cannot be resolved at the patient-physician-family level, or when families and hospital personnel hospital differ with regard to the use of a specific treatment, judges are called upon to intervene. Legislation, court decisions, and government regulations have evolved to form a bioethical *corpus juris* with profound repercussions that extend beyond the clinical context. In this sense, bioethics is probably the field of study that most faithfully reflects the contemporary era.

Finally, bioethics is not a field of study limited solely to the academic realm. It is also a social and cultural phenomenon about which the public receives information via newspapers and television, which increasingly are examining the doctor - patient relationship, human reproduction, genetic research, transplants, AIDS, the processes of death and dying, access to health services, health financing, and the allocation of health resources.

In summary, medicine and health are social activities with profound ethical consequences. As science and technology increase their ability to intervene in processes that regulate or alter life, there is an increased need to subject their use to ethical considerations. Bioethics is an inexorable challenge of our times with implications for the future. The theoretical and applied study of bioethics is a field in which medicine, law, philosophy, theology, the social sciences, and the related health care professions can contribute their knowledge and experience.

A. International Bioethics Movement

During recent decades, numerous centers, institutes, and education and research programs have been established in the field of bioethics, especially in the developed world. The Hastings Center in New York (1969) and the Kennedy Institute of Ethics at Georgetown University (1971) have exerted a powerful influence throughout the world. There are more than 45 centers and institutes in the United States of America, 10 in Canada, and a growing number in the European countries. The Council of Europe has established an *ad hoc* Committee of Experts in Bioethics (CAHBI), which has formulated important recommendations for areas such as medical research using human subjects and the selective use of prenatal genetic testing. UNESCO created a bioethics unit in December of 1992.

The Council for International Organizations of Medical Sciences (CIOMS), acting on its own and in association with WHO, has focused on issues of medicine, human rights, and ethics in the last decade. Most of the developed countries and some developing countries have national bioethics commissions.

In October 1992, the International Association of Bioethics was founded in Amsterdam; most of the bioethics centers and institutes and most scholars interested in bioethics throughout the world belong to this association.

B. Bioethics in Latin America and the Caribbean

For some time now efforts have been under way to study and teach bioethics in Latin America and the Caribbean, but only recently has this discipline become a component of the programs of some schools of medicine and nursing. In several countries important initiatives have been launched. Examples include, in La Plata, Argentina, the Mainetti Foundation, which incorporates the Institute of Medical Humanities (1972), the Bioethics Center (1988), and also a Latin American School of Bioethics; in Colombia, the Center for Medical Ethics of the Colombian Association of Schools of Medicine (1988); in Chile, the Center of Bioethics and Humanistic Studies at the School of Medicine of the University of Chile (1988) and the Bioethics Unit at the School of Medicine of the Catholic University of Chile (1988); and in Uruguay, the Bioethics Department of the Catholic University of Uruguay (1986) and the Committee on Ethics of the Medical Union of Uruguay (1991).

In the mid-1970s Cuba instituted committees at the hospital level to resolve clinical conflicts and a system of special legal advisory services to deal with complaints from patients.

In addition, notable interest and concern about bioethics has been expressed in academic circles and within ministries, businesses, the judicial system, and the political arena, as well as among the general public, and these concerns transcend national borders. There has been an increase in the coverage of bioethics issues in the mass media, and in almost all the countries seminars have been organized on specific issues. PAHO/WHO is receiving a growing number of requests for information, support for attendance at conferences, assistance in the organization of meetings, and funds to attract renowned experts to speak on bioethics.

Bioethics has become an important component of political programs, as well. The peoples of Latin America and the Caribbean are demanding equity within the health care system and they are increasingly expressing their concern over such issues as the allocation of resources, reproduction, population, the rights of patients, death and the process of dying, medical research, and the environment.

C. Activities of PAHO

PAHO's concern with the field of the bioethics during recent years has been reflected in the following activities:

- The publication of special issues of the *Boletín de la Oficina Sanitaria Panamericana* and the *Bulletin of the Pan American Health Organization* devoted to bioethics (vol. 108, nos. 5 and 6, May and June 1990, in Spanish and vol. 24, no. 4, 1990, in English) with a pressrun of some 11,000 copies, which was quickly exhausted, marked an important milestone in the Region. These issues of the *Boletín* are being utilized as study texts in numerous universities and are being consulted as essential reference materials. The content of the *Boletín* was reprinted in Scientific Publication No. 527: *Bioethics - Temas y perspectivas* (1990) (also published in English: *Bioethics - Issues and Perspectives* (1990)), which have been as successful as the *Boletín* articles.
- Scientific Publication No. 530, *Aportes de la ética y el derecho al estudio del SIDA* (1991) (in English: *Ethics and Law in the Study of AIDS* (1992)), financed in part by a generous contribution from the Federal Centre for AIDS in Canada, contains the results of a successful Regional Consultation on the subject, held in Santiago, Chile, in October 1990, with financing from the WHO Global Program on AIDS.
- Participation in specialized conferences and meetings on bioethics as a very partial response to the numerous requests and invitations that have been received.
- Information and opinions about bioethical issues in response to requests from government and university entities and individual investigators.
- Articles in specialized journals.
- Organization of a data base with information on individuals and institutions concerned with bioethics;
- Institutional contacts with the principal centers and institutes of bioethics throughout the Region and in the rest of the world.

II. IMPORTANCE OF THE PAN AMERICAN INSTITUTE OF BIOETHICS

1. Importance of bioethical issues

The aim of the Pan American Institute of Bioethics (*BioEthics*) is to meet a critical need in health development and to make a direct contribution to the Member Countries in order to help improve the delivery of health care and enhance the relationship between health and society. The development and promotion of the Institute's mission is a necessary contribution that can help improve the delivery of health care in the Region. Its importance is made apparent by the following discussion of several aspects of the Institute's work:

A. Decision-making processes

An important contribution of *BioEthics* will be its collaboration in the development of processes whereby decisions can be reached and conclusions drawn which are supported by the ethical and moral standards recognized in a given environment. This applies to all levels of health care delivery, from the formulation of health policies to the resolution of clinical conflicts.

B. Specific bioethical issues

a) Recognition of patients' rights

In the doctor-patient relationship there is an inherent imbalance of power. The physician possesses the knowledge and the skills that the patient needs in order to get better. The physician also enjoys an elevated status in society. Furthermore, the patient seeks the assistance of the physician when he is sick and thus, vulnerable. Vulnerable, weak, and needy human beings have to be protected, and it is not advisable to leave the task of balancing the individual rights of patients in the hands of medical authorities alone. The application of bioethics can lead to the formulation of guidelines, norms, and standards for the delivery of health care in such a way that basic rights are safeguarded and the freedoms and rights of all members of society are enhanced.

b) Need for health care and societal demand

Throughout the world there has been a growing interest in the issues of bioethics, and this has been equally true in Latin America and the Caribbean. A number of issues are being aired by the communications media and debated by professional associations and other organizations and interest groups, and these issues need to be dealt with in an objective and informed manner.

Only through the promotion and the dissemination of bioethical ideas, principles, and approaches will it be possible to meet this pressing need constructively and continuously. The capacity of bioethics to address the ethical dilemmas so characteristic of modern societies can provide fundamental assistance to the leaders of society, both in the political and professional realms.

c) Challenges of scientific progress

Both medical technology and scientific progress are advancing at a staggering pace and society's capacity to respond to the possible consequences of these developments is being sharply tested. Not all the potential results of technological development are likely to be beneficial, and some may prove detrimental if the consequences of some new technologies are not weighed carefully. Only with sound ethical standards and carefully formulated policies--with due account taken of ethical implications--will it be possible to anticipate and avoid undesirable situations.

d) Experimentation and research using human subjects

Disregard for basic standards in research using human subjects gave rise, in the aftermath of the Second World War, to a radical questioning of ethics and society in the modern age, which brought with it the need to give new conceptual and applied meaning to ethics. It is essential, when medical professionals utilize human subjects for their research, that they be able to guarantee respect for each of the participants.

Research on human subjects takes place throughout Latin America and the Caribbean, and therefore it is necessary to have adequate standards and facilities to examine research projects. Through the training of personnel and the formulation of standards substantial headway can be made toward meeting this need.

C. Consideration of specific gender-related needs in the delivery of health care

Traditionally, health care systems have not attached sufficient importance to the specific needs of either sex. In the case of women, it is essential that care not be limited exclusively to the area of reproductive health.

Health care providers need to be aware of the differences in the roles and the outlooks of men and women. The contribution of bioethics will be to provide a forum in order to improve the capacity for perception of these differences.

The incorporation of perceptions about gender, supported by the values and the experiences of Latin America and the Caribbean, will make it possible for health policy and health care to become more appropriate and acceptable for the peoples of the Region.

D. Cross-cultural problems

Bioethical thinking encompasses both universal principles and standards and specific features of the culture in which it occurs. Thus, the wealth of diverse cultures can help to vitalize the general values and make it possible, at the same time, to propose options to enhance bioethical thought. In turn, cross-cultural perspectives, in linking various cultures, make it possible to assess the multiplicity of manifestations and expand the range of considerations that it may be important to weigh in academic discussion and in the proposal of public policies.

The Institute will encourage cross-cultural studies in bioethics, which will be facilitated by the multiplicity of contacts with centers and institutes concerned with bioethics in different parts of the world.

2. Role of PAHO/WHO

One of the basic missions of PAHO/WHO is to help to improve the health of the peoples in the Region of the Americas. Accordingly, it is appropriate for PAHO/WHO to take the lead in making the respectable practice of bioethics a reality in Latin America and the Caribbean. PAHO/WHO is committed to health promotion in its broadest sense in every country of the Americas. Although its activities are aimed mainly at the countries of Latin America and the Caribbean, its relations with institutions in the United States of America and Canada and in other parts of the world (France, the United Kingdom, and the Netherlands are Participating Countries of PAHO because they have territories in the Region) have made PAHO/WHO, over its 90 years of existence, a unique organization.

PAHO/WHO can ensure the political neutrality, objectivity, and pluralism necessary for the progress of bioethics in Latin America and the Caribbean. Given the complexity of the issues encompassed by bioethics it is impractical to think that a single correct action, response, or method can be found. There are certain concepts, policies, and standards that are recognized internationally, and these are at the heart of the main currents of bioethical thought. There are, however, genuine dilemmas that are open to a variety of apparently reasonable interpretations. Solid and serious international cooperation for research, discussion, and reflection are imperative in order to gain a true perspective in Latin America and the Caribbean and in order to make continuous contributions to the development of bioethics.

PAHO/WHO is in a position to play several indispensable roles in order to ensure the success of this initiative, thanks to: its technical capability; its regional infrastructure of representative offices, centers, and institutes; its ties to the world health system; its power to bring people together; its experience with proposals for research protocols; and its experience in the administration of the principal international programs. No other organization in Latin America or the Caribbean can offer the kinds of services that PAHO/WHO can provide for the development of bioethics in the Region in the context of the international bioethics movement.

3. Role of the University of Chile

The University of Chile, which celebrated its 150th anniversary in 1992, is a secular national institution of higher education which affords access to advanced contemporary knowledge and to ongoing debate regarding solutions to the principal problems of today's society. It occupies a leadership position in undergraduate and graduate-level courses and in continuing and community education. It offers all the principal courses of study (medicine, law, social sciences, philosophy and humanities, education, and the arts). Throughout its history, the university has trained professionals from many countries of the Region and has exercised broad international influence.

In view of the fact that bioethics is a combination of theoretical and practical knowledge, it would be presumptuous for an international organization like PAHO/WHO to attempt to carry out this task without academic support. The recognition, support, and institutional participation of an important university is a necessary condition for the success of this effort. The University of Chile, one of most prestigious in Latin America, is at the vanguard in responding to the bioethical challenge and in offering its experience and facilities to PAHO/WHO in this joint undertaking.

III. MISSION OF *BioEthics*

The mission of the Pan American Institute of Bioethics will be to cooperate with the Member States of the Organization and their public and private entities in the theoretical, normative, and applied development of bioethics and its relationship to health.

IV. FUNCTIONS OF *BioEthics*

BioEthics will have the following functions:

1. Forum

BioEthics will provide a permanent forum for a broad, objective, and pluralistic discussion of bioethical issues at a high academic and technical level. Cross-cultural discussion and the exchange of information on the various issues of bioethics are fundamental. This function will make it possible for scholars from Latin America and the Caribbean to participate in an ongoing dialogue on bioethics with scientific and technical communities throughout the world. At the same time, the Institute, located within the university, will provide academics and professionals of the developed world with an opportunity to interact with their colleagues in Latin America and the Caribbean, helping to improve communication and international coordination of bioethics activities in the Region.

2. International study and research

The Institute will carry out studies and research at the national, subregional, and international level, in cooperation with bioethics centers in the Region and around the world. It will focus special energy on the development and supply of resources for the member countries in universities, ministries, nongovernmental organizations, and in the bioethics centers already in operation.

The areas for international study and research include: the significance, implications, and place of new technology; the relationships between medicine, biology, culture, morals, traditions, values, and legal institutions; the ecological aspect of medical technology; the dangers associated with the medicine of tomorrow; the repercussions of modern biomedicine on society; the influence of bioethics on philosophy, law, and other disciplines; human reproduction and the definition of death.

3. Teaching and training

The Institute will conduct teaching and training in bioethics at various levels. Programs will be formulated for the education and training of the members of committees for the review of research projects and for the members of the clinical ethics committees. In addition, the Institute will regularly offer basic intensive courses in bioethics, as well as seminars and workshops on specific issues, which will be open to professionals and other interested persons from various fields.

The preparation of candidates to sit on committees for the review of research projects will be a priority. This will include the formulation of problem-solving strategies, basic training in the sciences, international guidelines for the evaluation of research projects, and international ethical standards. Other programs will be concerned with clinical ethics committees, the preparation of instructional materials, and interdisciplinary approaches blending philosophy and bioethics, medicine and bioethics, law and bioethics, and theology and bioethics.

Because bioethics is a very broad field, the Institute's training and education program will also be broad. Initially, basic courses and training seminars will be offered to examine the specific practical problems associated with medical research using human subjects, the conflicts generated by the use of new therapeutic technologies, and urgent social issues relating to public health and access to health care. At the beginning there will be a special effort to train professionals, who will in turn be able to train students and young professionals at their own institutions. It is anticipated that there will be visits to the principal public and private medical establishments and universities in each country in order to draw the attention of staff and professors to bioethics and to begin preparations for incorporating bioethics as a component in professional training programs.

4. **Information**

The Institute will act as an information clearinghouse and reference center on bioethics in Latin America and the Caribbean. For this purpose, a regional system of bioethics information will be formed. Activities in this area will include: dissemination of information and replies to inquiries from users in any place in the various countries via electronic mail; collection of material on bioethics produced in Latin America and the Caribbean, in keeping with the standards established by the National Reference Center for Bioethics Literature of the Kennedy Institute of Ethics; close collaboration with the PAHO/WHO programs in the distribution of scientific information; incorporation of relevant bioethical material produced in other languages and in the rest of the world; translation of material; information services on literature, regulations, standards, and public discussions and debates regarding bioethics.

Thousands of bioethics titles are incorporated annually into collections on this topic, mainly in English. The lack of access to this wealth of information is one of the principal problems hindering the development of bioethics in Latin America and the Caribbean. Currently, very few materials on bioethics are being produced in the subregion, and publication of such materials therefore needs to be stepped up and brought into line with international standards. The Institute will make an effort to promote this activity. An important program conducted with the National Library of Medicine and the National Reference Center for Bioethics Literature of the Kennedy Institute of Ethics will make possible the installation of a specialized information center connected electronically, via BITNET, with the aforementioned Center. As more world-class literature is produced, *BioEthics* will compile and incorporate it into the system. Instructions and workshops on publications standards will be formulated. A basic reference library will be established.

5. **Extension work**

The Institute will participate in community activities and will deal with bioethics issues of general concern. It will also undertake to formulate strategies and prepare materials for community education, mainly audiovisual materials. It will be possible to utilize the HISPASAT satellite communication system for these activities, once an agreement between PAHO/WHO

and HISPASAT has been signed. This will make it possible for *BioEthics* to reach a large number of people in different countries by satellite.

Issues in bioethics are of interest not only to scholars, professionals, and health care administrators but also to society as a whole. As a result, it is necessary to endeavor to transmit information that has educational value to the widest possible audience. Efforts will be made to disseminate information, taking advantage of the benefits of modern audio and video equipment. The facilities of the University of Chile and other institutions will be utilized to record classes on videotape and audio cassette with a view to extending their utilization and dissemination. In addition, some of the material that currently exists in English will be translated into Spanish, French, and Portuguese.

6. **Mobilization of resources**

An attempt will be made to attract resources of various types--human, technological, financial, informative, equipment, fellowship, etc.--for *BioEthics* and its activities. An ongoing effort will be needed to seek financing for the development of a medium-term program (5 years) of teaching and research activities. The expected outcomes are: *a*) the formation of a critical mass of persons with a grounding in bioethics in the countries of the Region; and *b*) the creation and fostering of a tradition of both theoretical and applied bioethics. Financial resources for *BioEthics* and its activities, as well as for cooperative projects and various activities with other national and international institutes will be sought from national and international sources.

It is planned to establish a consortium of donors as a strategy for obtaining the financial resources to get the Institute off the ground, although contact will be maintained with these donors even after the Institute is operating. The resources obtained will be allocated mainly for work with the member countries in the development and strengthening of their own national initiatives in universities, ministries, businesses, nongovernmental organizations, and independent projects in bioethics. The mobilization of resources will also play an important role in making possible joint studies and research with centers and institutes in the developed world. These semipublic enterprises are very important for facilitating cross-cultural studies and in the exchange of ideas and opinions about common problems. Inasmuch as *BioEthics* will have minimum staffing needs (thanks to the resources to be furnished by the University of Chile and the Government of that country), most of the funds mobilized will be applied to the programs, projects, and activities planned for the direct benefit of the member countries and to related tasks.

7. **Technical cooperation**

The Institute will provide opportunities for informed discussion and decision-making on bioethics issues at the public and private level. It will collaborate with universities and with teaching centers and institutes and it will aid the formation of associations or networks of bioethics institutions in the Region.

One of the principal tasks of PAHO/WHO is the provision of technical cooperation to the member countries. It has many instruments for delivering this technical cooperation, and all will be brought to bear in *BioEthics*. However, it is anticipated that technical cooperation will mainly take the form of studies on specific issues, publication of the most current documents on certain subjects, and technical observations on bioethics proposals. Another dimension has to do with the increasingly important role centers and institutes play as experts whose opinion is recognized as valid by courts, legislatures, and governments. Technical cooperation in the form of institutional development of national capabilities will be the most visible expression of BioEthics's technical cooperation.

In addition, *BioEthics* will have an important function to fulfill in the enrichment and expansion of programs to other centers and institutes, since it will complement such programs, both in theoretical and in applied terms.

The PAHO/WHO technical programs deal with many bioethics-related issues. In addition, the PAHO/WHO centers and institutes are currently concerned with issues that call for and can benefit from bioethical input. One of the tasks of *BioEthics* will be to provide theoretical and applied modules in bioethics, for example in relation to maternal and child health issues, bioethics and neonatal care, bioethics and the environment, bioethical problems in veterinary public health, and bioethics in nutrition.

V. OPERATION OF *BioEthics*

1. Affiliation with PAHO/WHO

The Pan American Institute of Bioethics will carry out its activities as a decentralized affiliate of PAHO/WHO, under the supervision of the Office of the Director/Deputy Director of PAHO.

Administrative, financial, and accounting management; staffing; the procurement, import, and export of services; and auditing will be carried out in keeping with the policies, standards and regulations of PAHO/WHO. *BioEthics* will not be subject to national control, either in administrative or fiscal terms.

The Government of Chile will extend to *BioEthics* the privileges and immunities that PAHO/WHO enjoys in Chile.

2. Advisory bodies

The Director of PAHO will have general responsibility for the operation of *BioEthics*. Two advisory bodies will guide the Director of PAHO in the fulfillment of his responsibilities:

a) The International Scientific and Technical Council will advise the Director of PAHO on the general orientation of the Institute, its strategies of action, the mobilization of

resources, and the Institute's relations with other entities and programs in order to strengthen its action, as well as in the identification of priority issues and the scientific and technical evaluation of its program of work.

The Council will be made up of seven people, with individual responsibility, named by the Director of PAHO for renewable terms of three years. Balanced representation will be sought from a geographical, professional, and disciplinary point of view.

The Director of PAHO and the Rector of the University of Chile will be members *ex officio* of the Council.

The Organizations that participate in **BioEthics**, the principal donors and contributors, and other individuals and entities may be invited by the Director of PAHO to participate as observers on the Council.

The Council will be convened by the Director of PAHO and will hold one regular meeting a year.

b) The Program Committee for Chile will advise the Director of PAHO on the programming, execution, and evaluation of the activities carried out by the Institute in Chile, as Host Country, for the benefit of public and private national institutions.

The Committee will be composed of:

- The Rector of the University of Chile, or a representative designated by him;
- The Minister of Health, or a representative designated by him, and
- Two (2) representatives of PAHO/WHO.

The National Commission on Scientific and Technological Research and other public and private national entities with which collaborative relations are maintained may be invited as observers to the Committee.

The Committee will hold regular meetings at least twice a year at the headquarters of the Institute, and will be convened by the Director of PAHO or by the Director of the Institute, by designation. Special meetings may be held at the initiative of the Director of PAHO or at the request of the Government and the University.

3. Relations with the University of Chile

Relations, both academic and administrative, with the University of Chile will be managed at two levels: a) political, between the Director of PAHO and the Rector of the University, and b) technical and administrative, between the Director of **BioEthics** and the Bioethics Committee of the University of Chile. One of the special features of **BioEthics** will be its association with the University in the sense that it is intended to be something more than an international enclave within the University. While **BioEthics** will be administered and will

function as an international entity, it will also constitute a component of the academic capacity of the University of Chile and of the University's service to the community. In addition, *BioEthics* will be an extension of the University that will reach beyond national borders, since the University will accredit the training and the teaching imparted at *BioEthics* and it will co-sponsor some of the research proposals. Cooperation between *BioEthics* and the professors, schools, and institutes of the University will be coordinated by the Bioethics Committee of the University of Chile. Work with other universities will be carried out under a similar procedure.

4. Relations with the host country

Relations between *BioEthics*, as an affiliate of PAHO/WHO, and the Government will be overseen by the Ministry of Foreign Affairs of Chile.

5. The consortium and the interinstitutional network

BioEthics will be a regional program of universal scope. Accordingly, everything possible will be done to incorporate *BioEthics* into activities in bioethics at the world level. For this purpose, *a*) a consortium of bioethics centers/institutes in the developed world will be established by means of agreements for teaching and training, research, exchange of information, and contacts between people working in bioethics; and *b*) a network of institutions in Latin America and the Caribbean will be established in order to carry out joint projects and activities in teaching, training, research, extension, and information on bioethics.

Relationships will be established with institutions such as the Kennedy Institute of Ethics at Georgetown University in Washington D.C., the Hastings Center in New York, the Park Ridge Center in Chicago, the International Bioethics Institute in California, the Bioethics Center of the University of Toronto, the McGill Center for Medicine, Ethics, and Law in Montreal, and the Center for Human Bioethics of Monash University in Australia. Contacts will be established with centers and institutes in the United Kingdom, France, and the rest of Europe with a view to encouraging them to join the consortium. The Center for Bioethics of the Mainetti Foundation of Argentina and the Center for Medical Ethics of the Colombian Association of Schools of Medicine are examples of some of the institutions that will be invited to join the bioethics network in Latin America and the Caribbean. The promotion, strengthening, and development of these institutions will be an important aspect of the technical cooperation program in bioethics. The objective of *BioEthics* will be to strengthen national capabilities, not to replace them.

6. Human resources

A minimum contingent of permanent staff will be maintained. The Director and Administrator and any other personnel whom the Director of PAHO may consider necessary will be international civil servants subject to the standards and regulations of the United Nations, although several hiring options are being studied with a view to reducing costs.

The short-term services of professors, investigators, and other experts from around the Region, in particular for teaching and research activities, will be obtained in accordance with PAHO/WHO hiring practices and in keeping with the standards and regulations that may be issued depending on the needs of *BioEthics*.

The technical personnel and academic and professional support staff assigned by the University of Chile, the Ministry of Health, and other national public or private institutions will retain their affiliation with their institution of origin, but will be subject to the work standards of the Institute during the period they are assigned to *BioEthics*. The same will be true with respect to human resources assigned to *BioEthics* from other member countries.

Technical and support services will be contracted for locally where activities are being carried out by the Institute.

7. Location of *BioEthics*

BioEthics will be located on property belonging to the University of Chile in Santiago. The building (measuring some 2,000m²), and the land (approximately 4,000m²) allotted to *BioEthics* will enjoy the same immunities to which PAHO/WHO is entitled and will have the corresponding independence and operational autonomy.

8. Evaluation after ten years of operation

After *BioEthics* has been in operation for 10 years, it is planned to carry out an evaluation of the work accomplished, its impact on the development of bioethics in the Region, and the significance of its contribution to the health of the peoples of the Americas. On the basis of this evaluation, the best mode of participation by the parties to the agreement on *BioEthics* will be determined.

VI. FINANCING

BioEthics will be funded by resources from the regular budget of PAHO and from the Government of Chile. Physical, logistic, and human resources will be provided by the University of Chile and the Ministry of Health of Chile .

PAHO/WHO will contribute resources from its regular budget in an amount not exceeding US\$600,000 a year.

The Government of Chile will contribute US\$200,000 per year.

The University of Chile will provide the physical resources: physical plant, at an estimated value of US\$1,500,000, and electricity, gas, and water at an estimated value of US\$25,000 per year. The amount that could otherwise be earned in rent is estimated at 8% of the value of the property, which implies an in-kind contribution equivalent to US\$120,000 per year. It is estimated that the personnel the University will assign to *BioEthics* permanently or temporarily (academics, professionals, technicians, and general services staff) will represent a contribution equivalent to US\$243,800. The estimated total contribution of the University per year is US\$403,800.

The Ministry of Health of Chile will contribute professional and technical personnel at a value equivalent to US\$70,200 per year, raising the contribution of the Government to US\$270,200 per year.

Efforts will be made to obtain, in addition, the short-term services of academics, professionals, and technicians from public and private institutions of the member countries.

Study and research proposals will be submitted to external sources.

The regional bioethics information system will operate with regular resources and funding from external sources.

Modular proposals for donations of equipment and furniture will be submitted (1994-1995).

Efforts will be made to mobilize voluntary contributions from the PAHO/WHO Member Governments.

Other sources of financing are expected to include grants, donations, and the sale of services (information, meetings, technical cooperation to private institutions).

The annual operating budget has been calculated at about US\$1,205,600. The monetary contribution of PAHO/WHO is estimated at US\$531,600 (44.1%). The in-kind and monetary contributions of the University of Chile, the Government of Chile, and the Ministry of Health are expected to total US\$674,000 (55.9%).

VII. REGIONAL TARGETS FOR TECHNICAL COOPERATION IN BIOETHICS

Since *BioEthics* will go into operation in 1994, the technical cooperation it provides during the 1994-1995 biennium will come under a single project integrating the activities related to the institutional development of *BioEthics*, its promotion and dissemination as a technical cooperation resource, and its gradual fulfillment of its various functions.

It is the mission of *BioEthics* to cooperate with the countries of the Region and their public and private entities in the theoretical, applied, and normative development of bioethics and its relationship with health.

The regional targets for technical cooperation during the 1994-1995 biennium will be:

- Consolidation of the institutional capacity of *BioEthics* at its headquarters and in its relations with institutions and individuals in the Member Countries.
- Establishment of academic ties with the University of Chile as a program of support in education, research, information, and extension.
- Promotion of pluralistic and objective discussion of bioethics.
- Promotion and dissemination of bioethics as an area of study, research, and regional cooperation.
- Training of human resources in bioethics at the regional level.
- Establishment and training of members of clinical ethics committees within health care services.
- Establishment and training of members of biomedical research review committees.
- Training in the context of professional associations (physicians, nurses, psychologists).
- Coordination of studies and research on bioethics.
- Development of the regional bioethics information system.

- Establishment of a consortium of entities to support *BioEthics* (Canada, United States of America, Europe).
- Identification, promotion, and development of a network of collaborating institutions to carry out activities in the Member Countries.
- Collaboration for the establishment of national bioethics commissions in the countries of the Region.

VIII. GLOBAL STRATEGY OF TECHNICAL COOPERATION

A. Priority needs in bioethics

In light of the growing attention that is being focused on bioethics by academia, government, and the general public it is important to hold regional forums (conferences, roundtables, colloquiums) that will help to define the context and the implications of bioethics in the countries of the Region.

At the health care level, the establishment of clinical ethics committees for decision-making, and the training of their members, is an immediate priority.

It is necessary to meet the need for duly established biomedical research review committees, with guidelines for their functioning and training for their members.

The development of bioethics at the academic level requires, first, the training of human resources and the preparation of educational materials in keeping with the reality of the situations in the countries.

The dissemination of existing information in bioethics and the generation of new information by the countries themselves is also an indispensable requirement.

B. General program objective of *BioEthics*

The program objective of *BioEthics* for the biennium will be (a) to consolidate its institutional capacity for service and to contribute to the development of national capacities for discussion, study, research, and consultation on bioethics in the search for national solutions to bioethical problems and dilemmas and to enhance equity in health, (b) to establish academic ties with the University of Chile as a program of support in education, research, information, and extension, and (c) to establish its connection with other entities inside and outside the Region for support and collaboration.

C. Specific program objectives of *BioEthics*

- To promote the development of national capacities for the discussion and generation of Regional approaches to bioethics through the creation/strength-ening of centers, institutes, and governmental and private-sector bioethics commissions at the central and local levels.
- To promote the development of knowledge in bioethics through a regional system of information in bioethics that will incorporate the latest developments, trends, results of studies and research, and policies.
- To develop educational materials for training in bioethics, and to create a critical mass of bioethicists in the Region.
- To promote the creation of clinical ethics committees and of biomedical research review committees.
- To train human resources in bioethics within health care systems, in the communications media, and in community organizations.
- To promote, support, and coordinate studies and research on bioethics with national and international entities.
- To promote the mobilization of national and international resources for the education/training, studies/research, information, and extension in bioethics.
- To collaborate in the development of national capabilities in bioethics in the Ministries of Health and social security health services.

D. Strategic orientations

- Establishment of program ties between *BioEthics* and the PAHO technical units and Centers/Institutes and with the University of Chile.
- Identification and compilation of a directory of people and institutions concerned with bioethics in the Region.
- Cooperation and coordination with specialized institutions for the establishment of a consortium and network of entities for support and collaboration.
- Training of human resources to provide training in bioethics, health services administration, research, and consulting.
- Establishment and training of clinical ethics committees and of biomedical research review committees.
- Development of educational materials and courses in bioethics.
- Studies and research on bioethics with emphasis on health services, local health systems, and the impact of bioethics on health policies.
- Establishment of a regional information system on bioethics.

IX. THE *BioEthics* PROJECT: PURPOSE, NATIONAL PRIORITIES, AND LINES OF ACTION

A. Purposes

- To contribute to the development of national capabilities in bioethics for the discussion and proposal of solutions to the dilemmas related to technology, ethics, and health.
- To cooperate in the design, coordination, and evaluation of clinical and public health studies and research on bioethics.
- To cooperate in the design, execution, and evaluation of bioethics programs in the Ministries of Health and social security health services.
- To cooperate in the education/training of human resources in bioethics.
- To cooperate in the establishment/training of clinical ethics committees and biomedical research review committees.
- To establish a regional bioethical information system.

- To mobilize resources in general for the development of national capabilities and for regional and subregional activities.
- To establish a network of interinstitutional relations of support for and collaboration with *BioEthics* in and outside the Region with a view to strengthening and universalizing development and cooperation in bioethics.

B. National priorities

- To cooperate with countries of the Region in the identification of the potential for development of national capabilities in bioethics.
- To provide professional training in various aspects of bioethics through courses, workshops, and seminars at *BioEthics* headquarters and in the countries.
- To train educators in bioethics through extended courses (four months).
- To compile a directory of people and institutions concerned with bioethics throughout the Region.
- To establish a program for cooperation with the Kennedy Institute of Ethics at Georgetown University and the Hastings Institute in New York. Formal contacts will be initiated, for the same purpose, with the National Institutes of Health of the United States of America, UNESCO, CIOMS, CAHBI of the Council of Europe, and other institutions concerned with bioethics in France, the Netherlands, and the United Kingdom (Participating Countries of PAHO), as well as Spain and Portugal (Observers).
- To establish a regional bioethics information system.
- To initiate a bioethical dissemination mechanism by means of letter - fax.
- To prepare at least two regional and subregional studies on the bioethics of mental retardation in children (Kennedy Foundation) and the bioethics of AIDS.
- To produce scientific publications on bioethics for external dissemination.
- To establish and train clinical ethics committees.
- To establish and train biomedical research review committees.

C. Lines of action

- a) Technical cooperation with the countries of the Region

Identification, cooperation, and coordination with entities and people concerned with bioethics in order to form a network of national nuclei for the exchange of information and experiences and for the execution of joint or collaborative activities in the Member Countries.

- Development of clinical ethics and biomedical research review committees.
- Training of members of ethics committees.
- Development of academic and applied training in bioethics.
- Informed discussion on bioethics issues affecting the health of populations that are potentially the subject of policy decisions.
- Development of the regional bioethics information system.

b) Development of human resources

Training of educators and trainers in bioethics; training of members of clinical ethics and biomedical research review committees; training of communications media professionals; training of health care personnel at the central level and within local health systems; multidisciplinary training. The training will be accomplished through seminars, workshops, and formal courses at **BioEthics** headquarters, and through courses and seminars conducted in the countries in collaboration with national entities.

c) Studies and research

Study and research protocols will be drafted with a view to contributing to the examination of bioethical aspects of health care, especially primary care.

d) Promotion and dissemination of bioethical information

Establishment (1994) and development (1994-1995) of the regional bioethics information system; training of professionals and technicians in bioethics information; courses in bioethics research and writing; network for dissemination of bioethics information by electronic means (via BITNET) to the BIOETHICSLINE of the Kennedy Institute of Ethics at Georgetown University, the National Library of Medicine at the National Institutes of Health of the United States of America; CD-ROM information services through the BIREME data bases and other PAHO/WHO data bases.

e) Institutional Development

To prepare and negotiate in 1994 a project for the institutional development of *BioEthics* with regular and external resources. To consolidate and strengthen the installed capacity of *BioEthics*; to identify and train human and institutional resources within and outside the Region to carry out education/training, study/research, information, and technical cooperation activities. The duration of the project will be two years.

f) General management activities

- Management and administration of *BioEthics*
- Development of policies, plans, and programs:
 - + Education/training/extension
 - + Studies/research
 - + Forum (conferences, colloquiums)
 - + Information
 - + Technical cooperation
- Mobilization of resources
- Dissemination of institutional information
- Training of personnel

Appendixes