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**PROGRESS REPORT ON THE ESTABLISHMENT OF THE PAN AMERICAN PROGRAM ON BIOETHICS
IN CHILE**

The Director of the Pan American Sanitary Bureau is pleased to report to the 111th Meeting of the Executive Committee regarding the establishment of the Regional Program on Bioethics.

Bioethics is a new applied field of study and research that is of universal interest and concern. Its influence in the scientific and technological community, in the sociocultural sphere, and in the political arena is considerable. In 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 the sort of pluralistic and objective dialogue that could facilitate frank 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 PAHO and the 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 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 on Planning and Programming (December 1992), the possibility of establishing a Pan American institute of bioethics was discussed. Based on the comments that were made, the document on the proposed institute was revised. Another option that was looked at was the establishment of a Regional program on bioethics in Chile.

At the 20th Meeting of the Subcommittee (April 1993), the option of setting up the Regional program was discussed. This option allows the original objectives to be achieved while devoting fewer resources to administration and emphasizing aspects of technical cooperation. As a result, (a) the documentation has been revised to present the initiative as the Regional Program on Bioethics, (b) the program area HBE, Promotion of Bioethics, has been included in the Organization's program classification, and (c) US\$760,000 has been proposed in the Program Budget 1994-1995 for the Regional Program on Bioethics.

In this document, the Director asks the Executive Committee to consider the importance of this topic and of the plans for the implementation of a Regional Program with the above-described objectives, with a view to formulating recommendations to the Directing Council on this matter.

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REGIONAL PROGRAM ON 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 by PAHO/WHO and the University of Chile to Create a Regional Program on Bioethics

The growing world concern about bioethics 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 an initiative of the Director of PAHO/WHO, Dr. Carlyle Guerra de Macedo, and the Rector of the University of Chile, Dr. Jaime Lavados Montes, to establish a program, directed by PAHO and closely associated with the University, in order to meet regional needs. The original idea was to establish a Pan American institute of bioethics.

The Government of Chile expressed an immediate and concrete interest, proposing that Chile serve as host country (Annex A). The University of Chile 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 financial, institutional, and personnel support.

The commitment of the Government of Chile and the University of Chile was reiterated by the Chilean delegation at the 36th Meeting of the Directing Council and at the 19th and 20th Meetings of the Subcommittee on Planning and Programming. The 20th Meeting (April 1993) approved the incorporation of the initiative into the Program Budget of PAHO/WHO in the form of a Regional Program on Bioethics.

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 problems 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 in the United States (Annex B). The growing number of international organizations addressing the issue of research on human subjects is another indicator of the fundamental importance of bioethics (Annex C).

Bioethics constitutes in itself a generalized cultural phenomenon which synthesizes the progress of biomedical technology and the serious ethical conflicts it generates. The application of new knowledge and techniques is characteristic of 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, the courts 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 that is 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, financing, and the allocation of resources to provide health care for populations.

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.

2.1 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.

2.2 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 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 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

2.3 Activities of PAHO

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

a) 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: *Bioética - Temas y perspectivas* (1990) (also published in English: *Bioethics - Issues and Perspectives* (1990)), which have been as successful as the *Boletín* articles.

b) 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.

c) Participation in specialized conferences and meetings on bioethics as a very partial response to the numerous requests and invitations that have been received.

d) Information and opinions about bioethical issues in response to requests from government and university entities and individual investigators.

e) Articles in specialized journals.

f) Organization of a data base with information on individuals and institutions concerned with bioethics;

g) Institutional contacts with the principal centers and institutes of bioethics throughout the Region and in the rest of the world.

II. IMPORTANCE OF THE REGIONAL PROGRAM ON BIOETHICS

1. Importance of Bioethical Issues

The aim of the Regional Program on 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 Program'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:

1.1 Facilitation of decision-making

An important contribution of the Regional Program on 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.

1.2 Specific bioethical issues

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. 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.

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.

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 challenged. 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.

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 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.

1.3 Gender-related considerations 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.

1.4 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, through cross-cultural perspectives that link various cultures, bioethics makes it possible to assess the multiplicity of cultural manifestations and expand the range of considerations that it may be important to weigh in academic discussion and in the proposal of public policies.

It is necessary to 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

The fundamental mission 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 the Americas. PAHO/WHO is committed to health promotion in its broadest sense in every country of the American continent. Although its activities are aimed mainly at the countries of Latin America and the Caribbean, its relations with institutions in the United States and Canada and in other parts of the world (France, the United Kingdom, and the Netherlands are Participating Governments of PAHO because they have territories in the Region; Spain and Portugal are Observers) have made PAHO/WHO an organization that is uniquely qualified to collaborate in this field.

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 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, an academic institution of international renown, 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 THE REGIONAL PROGRAM ON BIOETHICS

The mission of the Regional Program on 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 THE REGIONAL PROGRAM ON BIOETHICS

The Regional Program on Bioethics will have the following functions:

1. Forum

The Regional Program on 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 Regional Program, located within the University, will provide academics and professionals from 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. Technical Cooperation

The Regional Program 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 of them will be included in the Regional Program. However, it is anticipated that technical cooperation will mainly take the form of studies on specific issues, publication of documents providing up-to-date information on certain subjects, and technical observations on bioethics proposals. Another dimension has to do with the increasingly important role that 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 the Program's technical cooperation.

In addition, the Regional Program 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 technical programs and centers or institutes of PAHO/WHO deal with many bioethics-related issues. One of the tasks of the Program 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.

3. International Studies and Research

The Regional Program 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 mobilization of resources for the Member Countries in universities, ministries, and nongovernmental organizations, and in the bioethics centers already in operation.

The areas for international study and research include, inter alia, 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.

4. Teaching and Training

The Regional Program 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 Program will regularly offer basic intensive courses in bioethics, as well as seminars and workshops on specific issues for professionals and other interested persons from various fields.

The education of members of 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 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 aimed at training professionals, who will in turn be able to pass on what they have learned to 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

5. Information

The Regional Program will act as an information clearinghouse and reference center on bioethics in Latin America and the Caribbean. Activities in this area will include: dissemination of information and replies to inquiries from users 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; 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; and 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, most of them in English. The lack of access to this information source 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 Program 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 high-quality literature is produced, the Program will compile and incorporate it into the system. Instructions and workshops on publications standards will be formulated. A basic reference library will be established.

6. Extension Work

The Regional Program 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. An effort will be made 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 the Program to reach a wider public 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, an effort must be made to transmit information that has educational value to the widest possible audience. An effort 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.

7. Mobilization of Resources

An attempt will be made to attract resources of various types--human, technological, financial, or informative, or resources in the form of equipment, fellowships, etc.--for the Regional Program and its activities from national and international sources. An ongoing effort will be needed to seek financing for the development of a medium-term program (5 years) for the cooperation, teaching, and research activities.

It is planned to establish a consortium of donors as a strategy for securing the financial resources needed to get the Regional Program off the ground. The resources obtained will be allocated mainly for work with the Member States 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 the Program will have minimum staffing needs, most of the funds mobilized will be used for the programs, projects, and activities planned for the direct benefit of the Member States.

V. OPERATION OF THE REGIONAL PROGRAM ON BIOETHICS

1. Affiliation with PAHO/WHO

The Regional Program on Bioethics will carry out its activities as a decentralized program of PAHO/WHO, under the supervision of the Office of the Director/Deputy Director.

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. The Regional Program will not be subject to national control, either in administrative or fiscal terms.

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

2. Advisory Bodies

The Director of PAHO/WHO will have general responsibility for the operation of the Regional Program on Bioethics. Two advisory bodies will guide the Director of PAHO/WHO in the fulfillment of his responsibilities:

2.1 The International Scientific and Technical Council

The International Scientific and Technical Council will advise the Director of PAHO/WHO on the general orientation of the Regional Program, its strategies of action, the mobilization of resources, and the Regional Program'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/WHO for renewable terms of three years. Balanced representation will be sought from a geographical, professional, and disciplinary point of view.

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

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

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

2.2 The Program Committee for Chile

The Program Committee for Chile will advise the Director of PAHO/WHO on the programming, execution, and evaluation of the activities carried out by the Regional Program 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 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 Regional Program, and will be convened by the Director of PAHO/WHO or by the Director of the Regional Program, by designation. Special meetings may be held at the initiative of the Director of PAHO/WHO 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/WHO and the Rector of the University, and *b)* technical and administrative, between the Director of the Regional Program on Bioethics and the Bioethics Committee of the University of Chile. One of the special features of the Regional Program 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 the Program 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, it will accredit the training and the teaching imparted at the Regional Program and it will co-sponsor some of the research proposals. Cooperation between the Regional Program 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 the Regional Program on Bioethics as a program of PAHO/WHO and the government will be overseen by the Ministry of Foreign Affairs of Chile.

5. The Consortium and the Interinstitutional Network

The Regional Program on Bioethics will be a Regional program of universal scope. Accordingly, everything possible will be done to incorporate the Program 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 Regional Program 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 the Regional Program on 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 any other personnel whom the Director of PAHO/WHO may consider necessary will be international civil servants

subject to the standards and regulations of the United Nations, although several hiring options will be explored with a view to reducing costs.

The short-term services of professors, investigators, and other experts from around the Region, in particular for technical cooperation, 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 the Regional Program.

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 Regional Program during the period they are assigned to that Program. The same will be true with respect to the human resources assigned to the Program from other Member States.

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

7. Location of the Regional Program on Bioethics

The Regional Program will be located on property belonging to the University of Chile in Santiago. The building allotted to house the Program will enjoy the same immunities to which PAHO/WHO is entitled and will have the corresponding independence and operational autonomy

8. Evaluation after Five Years of Operation

After the Regional Program on Bioethics has been in operation for five 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 the Regional Program will be determined.

VI. FINANCING

The Regional Program on Bioethics will be funded by resources from the regular budget of PAHO/WHO 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\$380,000 a year.

The government of Chile will contribute at least US\$100,000 per year. The Ministry of Health of Chile will contribute financial resources in the amount of \$100,000 a year and professional and technical personnel at a value equivalent to \$70,200 per year, increasing the government's contribution by \$170,200 per year.

The University of Chile will provide the physical plant and cover the cost of electricity, gas, and water at an estimated value of US\$92,000 per year. It is estimated that the personnel the University will

assign to the Regional Program either permanently or temporarily (academics, professionals, technicians, and general services staff) will represent a contribution equivalent to \$160,800. Other facilities available from the University are equivalent to \$25,000 a year (auditoriums, audiovisual equipment, etc.). The total estimated contribution from the University is \$277,000 a 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 States.

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 States.

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\$827,000. The monetary contribution of PAHO/WHO is estimated at \$380,000. The in-kind and monetary contributions of the University of Chile and the Government of Chile are expected to total \$447,000.

VII. REGIONAL GOALS FOR TECHNICAL COOPERATION IN BIOETHICS

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

The Regional goals for technical cooperation during the 1994-1995 biennium will be:

1. Consolidation of the institutional capacity of the Regional Program on Bioethics at its headquarters and in its relations with institutions and individuals in the Member States.
2. Establishment of academic ties with the University of Chile as a program of support in education, research, information, and extension.
3. Promotion of pluralistic and objective discussion of bioethics.
4. Promotion and dissemination of bioethics as an area of study, research, and regional cooperation.
5. Training of human resources in bioethics at the Regional level.

6. Establishment and training of members of clinical ethics committees within health care services.
7. Establishment and training of members of biomedical research review committees.
8. Training in the context of professional associations (physicians, nurses, psychologists).
9. Coordination of studies and research on bioethics.
10. Development of the regional bioethics information system
11. Establishment of the consortium of entities to support the Regional Program on Bioethics (Canada, United States, Europe).
12. Identification, promotion, and development of a network of collaborating institutions to carry out activities in the Member States.
13. Collaboration for the establishment of national bioethics commissions in the countries of the Region.

VIII. GLOBAL STRATEGY OF TECHNICAL COOPERATION

1. Priority Needs in Bioethics

In light of the growing concern over bioethics in academia, the professions, health services, 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 and trained 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.

2. General Program Objective of the Regional Program on Bioethics

The program objective of the Regional Program on 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.

3. Specific Program Objectives of the Regional Program on Bioethics

- To promote the development of national capacities for the discussion and generation of Regional approaches to bioethics through the creation/strengthening of governmental and private-sector bioethics centers, institutes, and 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.

4. Strategic Orientations

- Establishment of program ties linking the Regional Program on Bioethics with 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 REGIONAL PROGRAM ON BIOETHICS: PURPOSE, NATIONAL PRIORITIES, AND LINES OF ACTION

1. Purpose

- 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 the Regional Program on Bioethics inside and outside the Region with a view to strengthening and universalizing development and cooperation in bioethics.

2. National Priorities

- To cooperate with at least 15 countries of the Region in the identification of the potential for development of national capabilities in bioethics.
- To provide training for about 500 professional in various aspects of bioethics through courses, workshops, and seminars at the Regional Program on Bioethics headquarters and in the countries.
- To train at least one educator in bioethics per country 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 Regional Program in New York. Formal contacts will be initiated, for the same purpose, with the National Regional Programs 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 Governments 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 at least 10 scientific publications on bioethics and 20 for external dissemination.
- To establish and train clinical ethics committees.
- To establish and train biomedical research review committees.

3. Lines of Action

3.1 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 States.

- 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.

3.2 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 the Regional Program

on Bioethics headquarters, and through courses and seminars conducted in the countries in collaboration with national entities.

3.3 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.

3.4 Promotion and dissemination of bioethical information

Establishment (1994) and development (1994-95) 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 through electronic access (via BITNET) to the BIOETHICSLINE of the Kennedy Institute of Ethics at Georgetown University and the National Library of Medicine at the National Institutes of Health of the United States; and CD-ROM information services through the BIREME data bases and other PAHO/WHO data bases.

3.5 Institutional development

Preparation and negotiation in 1994 of a project for the institutional development of the Regional Program on Bioethics with regular and external resources. Consolidation and strengthening of the installed capacity of the Regional Program on Bioethics; identification and training of 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.

3.6 General management activities

- Management and administration of the Regional Program on Bioethics
- Development of policies, plans, and programs: (1) Education/training/extension, (2) Studies/research, (3) Forum (conferences and colloquiums), (4) Information, (5) Technical cooperation.
- Mobilization of resources
- Dissemination of institutional information
- Training of personnel

ANNEXES

ANNEX A

Santiago, 8 May 1992

Dr. Carlyle Guerra de Macedo
Director
Pan American Health Organization
World Health Organization
525 23rd Street, N.W.
Washington, D.C. 20037

Dear Dr. Macedo:

I am very pleased to take note of the proposal initiated by you and the Rector of the University of Chile, Dr. Jaime Lavados Montes, and endorsed by Dr. Jorge Jiménez de la Jara, Minister of Health, for the establishment of a Pan American Institute of Bioethics to be located at the University of Chile.

Technological progress brings with it a moral challenge that affects all of humankind. Its impact on knowledge, values, and perceptions, as well as on the meaning of life, health, and death, is not only a matter of concern but also an issue of academic and public interest, especially in the more developed countries. Our societies in Latin America and the Caribbean cannot and should not remain on the sidelines in the bioethical debate. The proposal of PAHO/WHO and the University of Chile to join efforts for the common benefit of our countries through study, research, the dissemination of information, technical cooperation, and a multifaceted discussion of the issues of bioethics is both timely and necessary.

Thus, Sir, with you as an intermediary, I wish to extend a formal offer to PAHO/WHO for Chile to be the Host Country of the Pan American Institute of Bioethics (BioEtica), one of the Organization's family of Centers and Institutes, and for it to have its headquarters at the University of Chile and be associated with that institution, with the support of the Ministry of Health. The Government of Chile and the University will assume the corresponding institutional and financial commitments in the agreement to be drawn up in due course.

I would be most pleased if you would convey this offer, as well as Chile's support of the creation of the Pan American Institute of Bioethics, to the decision-making bodies of the Organization so that the Institute of reference may be established in accordance with the schedule indicated by you in the proposal.

In reiterating this important commitment of the Government of Chile to PAHO/WHO, I would like to take the opportunity to commend you for your leadership in the promotion of health, well-being, and the ongoing quest for development with equity for the peoples of the Americas.

Accept, Sir, the assurances of my highest esteem and consideration.

(signed)

Patricio Aylwin Azócar
President of the Republic of Chile



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

525 TWENTY-THIRD STREET, N.W., WASHINGTON, D.C. 20037-2895, U.S.A.

CABLE ADDRESS: OFSANPA
FAX (202) 223-5971
TELEPHONE (202) 861-3200

IN REPLY REFER TO: DLA/L/083-92

29 June 1992

His Excellency
Patricio Aylwin Azócar
President of the Republic
Palacio de la Moneda
Santiago, Chile

Excellency:

It is my great pleasure to write to you in connection with your Government's endorsement of the Pan American Institute of Bioethics, to be established by the Organization in association with the University of Chile and with the support of the Ministry of Health of your country.

Your kind letter of 8 May 1992 concerning this matter has been received with special satisfaction. The interest and support you have expressed in regard to this initiative to systematize the development of bioethics is one more reflection of your leadership and genuine concern for the issues and problems that beset humankind and contemporary society. There is no doubt that the impact of science and technology on society and the individual are enormous and our countries must join in the conceptual and applied challenge of the bioethical debate.

Given the importance of the offer extended by you in the name of the Government of Chile and the University of Chile, I considered it appropriate to place the matter before the 109th Meeting of the Executive Committee of the Directing Council of the Organization, held this past 25 June, so that I could then inform you of the reaction of the Member Governments represented on the Executive Committee.

I am pleased to report that the Executive Committee has endorsed the idea, which will now be developed, in programming, institutional, and financial/budgetary terms, for presentation to the next meeting of the Subcommittee on Planning and Programming, which will be held at the Headquarters of the Organization next December. This is the next step in the established sequence that

is expected to lead to final approval of the initiative by the Directing Council in September 1993.

I would like to manifest to you, personally and on behalf of the Executive Committee of the Directing Council, our deep gratitude for Chile's support in this important initiative on bioethics, one of the most important issues of our day and one with extraordinarily far-reaching implications for the future. Allow me also to express our appreciation for the outstanding efforts of the Rector of the University of Chile, Dr. Jaime Lavados Montes, as well as those of the Delegation of Chile to the Directing Council, in this connection. I have every confidence that the preparations currently under way will culminate in the establishment of the Pan American Institute of Bioethics in Chile in accordance with the proposed timetable.

Let me take this opportunity to express my sincere thanks for your kind remarks concerning myself and my endeavors as Director of the Organization to enhance the health and well-being of the peoples of the Region.

Accept, Excellency, the assurances of my highest esteem.



Carlisle Guerra de Macedo
Director



PAN AMERICAN HEALTH ORGANIZATION

Pan American Sanitary Bureau, Regional Office of the

WORLD HEALTH ORGANIZATION



525 TWENTY-THIRD STREET, N.W., WASHINGTON, D.C. 20037-2295, U.S.A.

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TELEPHONE (202) 861-0200

IN REPLY REFER TO: DLA/L/084-92

1 July 1992

Dr. Jaime Lavados Montes
Rector
University of Chile
Central House
Alameda Bernardo O'Higgins
Santiago , Chile, Chile

Dear Dr. Lavados:

You will recall that about two months ago we had the opportunity to talk about the growing importance of bioethics in medical practice and its relationship to health and society. At that time we conceived the idea of creating a Pan American Institute of Bioethics in association with the University of Chile which would contribute to the conceptual and applied development of bioethics taking into account the cultural, normative, and institutional realities of our countries and, above all, national capacity in bioethics.

The interest and support of the University of Chile and the Government of Chile, expressed in a letter addressed to me by President Aylwin on 8 May 1992, bear witness to the strong commitment that you and the Chilean Government are willing to make to this important initiative.

I am pleased to inform you at this time that the 109th Meeting of the Executive Committee of this Organization's Directing Council has taken cognizance of the initiative and has decided to accept the generous offer of the Chilean Government and the University of Chile to host such an Institute.

The Executive Committee has requested me to develop a proposal that will cover the programming, institutional, and budgetary and financial aspects of this undertaking which would be submitted this coming December at the next meeting of its Subcommittee on Planning and Programming. This is a challenging and complex assignment, and it must be completed within a short period of time. I know

that we will be able to count on your full cooperation in order to ensure the success of the presentation to the Subcommittee, and after that to the Executive Committee and the Directing Council in June and September 1993, respectively. I have entrusted the task to Hernán Fuenzalida, who will coordinate for PAHO the pertinent arrangements and the work that needs to be done.

I would like to express to you my deep satisfaction with the course that events have taken in regard to the Pan American Institute of Biotechnology and also my sincere appreciation for your valuable and most welcome contribution.

I feel confident that our joint initiative will be successful in bringing our peoples closer to the enjoyment of health and well-being with equity.

Please accept the assurances of my esteem and consideration.



Carlyle Guerra de Macedo
Director

ANNEX B

NATIONAL REFERENCE CENTER FOR BIOETHICS LITERATURE

LIBRARY CLASSIFICATION SCHEME

- | | | |
|--|--|---|
| <p>1 Ethics</p> <ul style="list-style-type: none"> 1.1 Philosophical Ethics 1.2 Religious Ethics 1.3 Applied and Professional Ethics <ul style="list-style-type: none"> 1.3.1 General 1.3.2 Business 1.3.3 Education 1.3.4 Engineering 1.3.5 Government/Criminal Justice 1.3.6 International Affairs 1.3.7 Journalism/Mass Media 1.3.8 Law 1.3.9 Scientific Research 1.3.10 Social Work 1.3.11 Agriculture 1.3.12 Information Science <p>2 Bioethics</p> <ul style="list-style-type: none"> 2.1 General 2.2 History of Medical Ethics 2.3 Education/Programs <p>3 Philosophy of Biology</p> <ul style="list-style-type: none"> 3.1 General 3.2 Evolution and Creation <p>4 Philosophy of Medicine and Health</p> <ul style="list-style-type: none"> 4.1 Philosophy of the Health Professions <ul style="list-style-type: none"> 4.1.1 General 4.1.2 Philosophy of Medicine 4.1.3 Philosophy of Nursing 4.2 Concept of Health 4.3 Concept of Mental Health 4.4 Quality/Value of Life <p>5 Science/Technology and Society</p> <ul style="list-style-type: none"> 5.1 General 5.2 Technology Assessment 5.3 Social Control of Science/Technology <p>6 Codes of Professional Ethics</p> <p>7 Sociology of Medicine</p> <ul style="list-style-type: none"> 7.1 General 7.2 Medical Education 7.3 Professional-Professional Relationship <p>8 Professional-Patient Relationship</p> <ul style="list-style-type: none"> 8.1 General 8.2 Truth-Telling 8.3 Informed Consent <ul style="list-style-type: none"> 8.3.1 General 8.3.2 Minors/Parental Consent 8.3.3 Third Party Consent/Incompetents 8.3.4 Right to Refuse Treatment 8.3.5 Bills, Laws and Cases 8.4 Confidentiality 8.5 Malpractice <p>9 Health Care</p> <ul style="list-style-type: none"> 9.1 General 9.2 Right to Health Care 9.3 Health Care Economics 9.4 Allocation of Health Care Resources 9.5 Health Care Programs for Specific Diseases/Groups <ul style="list-style-type: none"> 9.5.1 General 9.5.2 Aged 9.5.3 Disabled Persons 9.5.4 Minority Groups and the Poor 9.5.5 Women 9.5.6 HIV Infection and AIDS 9.5.7 Minors 9.5.8 Fetuses 9.5.9 Substance Abusers | <ul style="list-style-type: none"> 9.6 Quality of Health Care/Ethics Committees 9.7 Drugs and Drug Industry <p>10 Sexuality</p> <p>11 Contraception</p> <ul style="list-style-type: none"> 11.1 General 11.2 Availability of Contraceptives to Minors 11.3 Sterilization 11.4 Failure of Contraception/Wrongful Birth <p>12 Abortion</p> <ul style="list-style-type: none"> 12.1 General 12.2 Position Statements 12.3 Moral and Religious Aspects 12.4 Legal Aspects <ul style="list-style-type: none"> 12.4.1 General 12.4.2 Interests of Woman/Fetus/Father 12.4.3 Interests of Health Personnel/Institutions 12.4.4 Bills, Laws and Cases 12.5 Social Aspects <ul style="list-style-type: none"> 12.5.1 General 12.5.2 Demographic Surveys 12.5.3 Abortion Counseling <p>13 Population</p> <ul style="list-style-type: none"> 13.1 General 13.2 Population Growth 13.3 Population Policy <p>14 Reproductive Technologies</p> <ul style="list-style-type: none"> 14.1 General 14.2 Artificial Insemination and Surrogacy 14.3 Sex Predetermination/Selection 14.4 In Vitro Fertilization and Embryo Transfer 14.5 Cloning 14.6 Cryobanking of Sperm, Ova, or Embryos <p>15 Genetics, Molecular Biology and Microbiology</p> <ul style="list-style-type: none"> 15.1 General 15.2 Genetic Counseling and Prenatal Diagnosis 15.3 Genetic Screening 15.4 Gene Therapy 15.5 Eugenics 15.6 Behavioral Genetics 15.7 Biohazards of Genetic Research 15.8 Patenting Organisms 15.9 Sociobiology 15.10 Genome Mapping <p>16 Environmental Quality</p> <ul style="list-style-type: none"> 16.1 General 16.2 Nuclear Power 16.3 Occupational Health <p>17 The Neurosciences and Mental Health Therapies</p> <ul style="list-style-type: none"> 17.1 General | <ul style="list-style-type: none"> 17.2 Psychotherapy 17.3 Operant Conditioning 17.4 Psychopharmacology 17.5 Electrical Stimulation of the Brain 17.6 Psychosurgery 17.7 Involuntary Civil Commitment 17.8 Right of the Institutionalized to Treatment <p>18 Human Experimentation</p> <ul style="list-style-type: none"> 18.1 General 18.2 Policy Guidelines/Inst. Review Boards 18.3 Informed Consent 18.4 Behavioral Research 18.5 Research on Special Populations <ul style="list-style-type: none"> 18.5.1 General 18.5.2 Minors 18.5.3 Women 18.5.4 Fetuses and Newborns 18.5.5 Prisoners 18.5.6 Mentally Disabled Persons 18.5.7 Elderly and Terminally Ill Persons 18.5.8 Military and Government Personnel 18.5.9 Foreign Nationals 18.6 Social Control of Human Experimentation <p>19 Artificial and Transplanted Organs/Tissues</p> <ul style="list-style-type: none"> 19.1 General 19.2 Hearts 19.3 Kidneys 19.4 Blood 19.5 Donation/Procurement of Organs/Tissues 19.6 Allocation of Organs/Tissues <p>20 Death and Dying</p> <ul style="list-style-type: none"> 20.1 General 20.2 Definition/Determination of Death <ul style="list-style-type: none"> 20.2.1 General 20.2.2 Bills, Laws and Cases 20.3 Attitudes Toward Death <ul style="list-style-type: none"> 20.3.1 General 20.3.2 Health Personnel 20.3.3 Family 20.3.4 Death Education 20.4 Care of the Dying Patient <ul style="list-style-type: none"> 20.4.1 General 20.4.2 Care of the Dying Child 20.5 Prolongation of Life and Euthanasia <ul style="list-style-type: none"> 20.5.1 General 20.5.2 Allowing Infants to Die 20.5.3 Bills, Laws and Cases 20.6 Capital Punishment 20.7 Suicide <p>21 International/Political Dimensions of Biology and Medicine</p> <ul style="list-style-type: none"> 21.1 General 21.2 War 21.3 Chemical and Biological Weapons 21.4 Torture and Genocide 21.5 Forced Feeding of Prisoners 21.6 International Migration of Physicians <p>22 Animal Welfare</p> <ul style="list-style-type: none"> 22.1 General 22.2 Animal Experimentation 22.3 Animal Production |
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ANNEX C

SELECTED INTERNATIONAL INSTRUMENTS (CURRENT OR IN PREPARATION) REGULATING RESEARCH ON HUMAN SUBJECTS

<u>Organization</u>	<u>Title</u>	<u>Status</u>
UN GENERAL ASSEMBLY (New York)	International Covenant on Civil and Political Rights (1966) (Article 7)	Final
WORLD MEDICAL ASSOCIATION (Ferney-Voltaire)	Declaration of Helsinki IV (September 1989)	Final (under review?)
WHO and CIOMS (Geneva)	Proposed International Guidelines for Biomedical Research Involving Human Subjects (1982)	Final (due to be superseded)
	International Guidelines for Ethical Review of Epidemiological Studies (1991)	Final
CIOMS	International Ethical Guidelines for Biomedical Research Involving Human Subjects	In preparation (likely to be finalized in 1992)
WHO	WHO Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products	In preparation (likely to be finalized in 1993)
COUNCIL OF EUROPE (Strasbourg)	Recommendation No. R (90) 3 to Member States Concerning Medical Research on Human Beings (February 1990)	Final (Explanatory Memorandum in preparation)
	Protocol (to proposed Framework Convention on Bioethics) on Medical Research on Human Beings	In preparation (date of finalization uncertain)
EUROPEAN COMMUNITY (Brussels)	Note for Guidance on Good Clinical Practice for Trials on Medicinal Products in the European Community (July 1990)	Final (entry into force: July 1991)
NORDIC COMMITTEE ON MEDICINES (Nordic Council)	Good Clinical Trial Practice (December 1989)	Implemented in all Nordic countries
WORLD PSYCHIATRIC ASSOCIATION	Declaration of Hawaii II (1983)	Final

ANNEX D

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