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THE REGIONAL PROGRAM ON BIOETHICS AND HEALTH RESEARCH

Research Coordination
Division of Health and Human Development
Pan American Health Organization
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THE REGIONAL PROGRAM ON BIOETHICS AND HEALTH RESEARCH

Fernando Lolas Stepke

Background and aims

The Regional Program on Bioethics (HBE), a component of the Division of Health and Human Development (HDP), was established by PAHO in 1993 through an agreement with the University of Chile and the Chilean Government (Resolution CD37.R9, 1993) and started in Santiago de Chile in 1994.

HBE constitutes an institutional response, pioneer among international organizations, to the dilemmas posed by the application of technosciences to the health field and to the need to provide equitative access to healthcare to the populations of the Americas and the Caribbean.

Bioethics is an integrative discipline in social discourse aiming at establishing bridges between disciplines, institutions, and persons. Its main tool is dialogue and manifests itself in social institutions designed for group deliberation: clinical ethics committees, research ethics committees, national commissions and ad hoc working groups. Its aim is to search for ways of arriving at consensus and thus contribute to the “ethical sustainability” of decisions related to health.

Under ethical sustainability it should be understood both the specification and participant, critical and culture-fair grounding of decisions regarding healthcare, basic and applied research, professional and technical training, and

1 Director, Regional Program on Bioethics, PAHO/WHO
   Providencia 1017, piso 7, Santiago, Chile. E-mail: lolasf@chi.ops-oms.org
public communication of information and attitudes. Common, pre-reflexive morality is explicated and submitted to dialogical analysis processes, which guarantee social legitimacy.

HBE fosters bioethical knowledge where it is lacking, supports incipient efforts where it is already established and provides a permanent service in relation to information and advice within technical cooperation in health. Its supranational and transdisciplinary character permits a pluralist, non-confessional approach⁴.

Activities

Among the actions undertaken in its five years of existence, participation in plans and programs of training should be mentioned, especially through monographic courses, conferences, and seminars. Courses for professionals, accredited by the University of Chile, have also been offered, with more than eighty graduates up to now and the presentation of bioethics topics to hundreds of persons⁵. The collaboration of faculty from the Complutense University of Madrid, Spain, and experts from various countries, is acknowledged.

HBE has also contributed to the public diffusion of topics and themes and has participated in teaching programs at different institutions through technical opinion, advice and assistance⁶.

⁴ More details can be obtained from the institutional server (http://www.paho.org) in the section corresponding to the Division of Health and Human Development.

⁵ HBE has sponsored and organized courses on fundamental and clinical bioethics. Those who approve may complement them with some electives and a thesis and thus be eligible to receive the Masters degree of the University of Chile. The courses have been directed by Prof. Diego Gracia Guillén from Complutense University Madrid and a selected staff from Spain and Latin America. Support has been provided by the Spanish Ministry of Health and the Ford Foundation to the University of Chile.

⁶ Sources for the activities of the program are the bulletin series “Bioética Informa”, edited by Rebeca Uribe, and the “Cuadernos del Programa regional de Bioética”, edited by Julio Montt and Juan Pablo Beca between 1994 and 1998.
In collaboration with the Research Program at PAHO it has conducted studies on ethical review in agencies funding biomedical research in the Region and on informed consent and scientific publication⁷. It also takes part in an educational program, aimed at children and adolescents, which places them in contact with ethical implications of science and technology employing cartoons, which depict selected episodes of history. This program receives support from the Ford Foundation⁸. HBE mediates between philosophers, social scientists, research experts and planners in relation to studies and activities related to individual and population health. Its Documentation Center, collaborating with the Regional Library of Medicine (BIREME) and outside experts, prepares a Spanish language bioethical Thesaurus and will contribute to the development of the Virtual Library in Health, a project of the Division of Health and Human Development. Through publications of different kinds, both electronic and printed maintains a network of persons and institutions informed about developments in the field and receives inquiries and suggestions.

Work of HBE is an instrument for the Programs and Centers of PAHO. Its main function is to collaborate with Representations, Divisions and Centers, as well as with external collaborating institutions, in order that their orientations and plans incorporate the ethical and humanistic dimension from their formulation stage. It is at the service of the overall orientations of PAHO in all areas. It might be said that its technical role is to articulate initiatives and formulate them in forms amenable to treatment within committees and considering “culture-fair” ethical principles.

⁸ CF. Final Report, Project “Interfaces in Bioethics”, Interdisciplinary Center for Studies in Bioethics, University of Chile and Regional Program on Bioethics (Ford 970-0325). An additional project along similar lines is already in the implementation phase (Ford 995-0899). Projects are grants to the University of Chile, which acts as the executive unit of the projects through the Center for Bioethics.
Basic philosophy informing HBE action is that in ethical matters PAHO should have a pro-active rather than a reactive role, anticipating problems and dilemmas before they appear.

**Goals and proposals**

Among the mid-terms goals, inclusion of bioethical thinking in health programs in the Region is one of the most important. It should be achieved through adequate knowledge of bioethical principles and their translation into policies and programs. Intense collaboration with organizations concerned with bioethics in the Region is also contemplated in order to strengthen interactions and develop a truly panamericanist thinking in sanitary and research ethics\(^9\). In order to accomplish this goal a wide plan of training in bioethics at different levels has been devised, including the general public and specialists, with the goal of reaching 10,000 professionals by the year 2001\(^{10}\).

Along with the usual activities of HBE, there is the strong need to conceptually develop an “index of moral vulnerability” which in a compact and accessible form summarizes those indicators most relevant for approaching inequities and risks to dignity and human rights which might exist in some countries.

By suggestion of HBE, PAHO Director assembled an International Advisory Board on Bioethics which helps examine the orientations and policies of the organization, evaluates the results of HBE and will help consolidate the specific contribution of the Region in an international context. The conclusions

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\(^9\) HBE acts in collaboration with the Interdisciplinary Center for Studies in Bioethics of the University of Chile. Further information in Lolas, F. Bioética en la Universidad de Chile. *Anales de la Universidad de Chile*, sexta serie, No. 8, December 1998.

\(^{10}\) The global project covers different audiences, from the general public to health professionals and it is based upon delegation of knowledge, attitudes, aptitudes and skills with monitors at different levels. It has been elaborated by Mahal da Costa and Roberto Mancini, with the collaboration of James Drane, and will be implemented by a selected group of people throughout the continent aided by Roxane Moncayo.
from the first meeting of this advisory body, in May 1999, devoted to examining research on human subjects, constitute a valuable contribution to researchers in the Americas and the Caribbean. This analysis coincides with a reevaluation of codes and international declarations and a generalized movement of reformulation of goals and procedures in health research.

Along with this advisory board, the members of which will stay two years in office, a wide working group has been constituted in Latin America and the Caribbean countries. It acts as network for the exchange of information and will help delineate communication policies and strategies for the establishment of the discipline of bioethics through bulletins and the publication “Acta Bioethica”, currently in a design phase. Meetings devoted to the mutual articulation of experts and health professionals are being prepared11.

Official declarations never miss the importance of ethical reasoning in service planning and evaluation, provision of care, biomedical research, and training of health professionals. Through the action of HBE PAHO gives concrete expression to those declarations and puts at the disposal of the Latin American and Caribbean communities a technical capacity for material an human resource management in order to obtain better health for all, with all and through all the inhabitants of the Region.

Perspectives on biomedical research

An appropriate agenda for scientific research in the Region of the Americas and the Caribbean must include, by its transcendence, the ethical dimension from its very inception. The founding meeting of the Directors Advisory

11 It should be emphasized that up to now the South American continent has been mostly a “receptor” of bioethical thinking and most efforts could be considered as “importation and adaptation” of foreign principles and doctrines. Both cultural tradition and valoric/beliefs structure of Latin American and Caribbean peoples should be adequately valued and shown to experts from other traditions in order to establish a truly enriching intercultural dialogue.
Board in Bioethics was devoted to human subjects research due to the importance and urgency of the topic.

Globalization of social processes associated to science and technology demand a revision of codes and declarations formulated in other contexts and circumstances. Most of them are responses to dilemmas and challenges at the time when they were drafted. The Nürenberg code, the Helsinki declaration or the CIOMS norms do not contain provisions appropriate to the current situation of research projects from industrialized countries carried out in underdeveloped ones. Reconsideration of them is necessary and urgent, especially in Latin America and the Caribbean. It is probable, as scientific literature indicates and is expressed by active researchers, that no regulation or code can replace good training of investigators or the moral climate of the community in which studies are performed. Trust in persons and institutions is still the best protection against abuses and excesses, albeit explicit formulation will never cease to be needed.

HBE not only studies the available literature. It also consults with experts as the ones convened in the International Advisory Board and conducts studies on current practices. Thus, a recent survey by Mancini, Lolas, and Pellegrini indicates that few national research funding agencies have their own ethics committee and most trust in those set up by the institutions requesting support.

The activity of ethics committees is considered by some biomedical scientists a bureaucratic burden to the conduct of investigations, concentrated on “rituals” associated with informed consent and without due coherence with the analysis of scientific merit. To stimulate clinical research is to face the dilemma of applying protocols designed in USA or Europe or adapting them to local practices. These protocols are sometimes demanding in aspects alien to Latin

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12 This study should be considered only the first of a series of investigations dealing with research practices in Latin America and the Caribbean. Publication practices in professional and research journals will be studied, along with an examination of the opinions of medical editors. Institutional practices in universities and academia will be the focus of attention.
American communities, in which individual autonomy does not play the same role as in the countries in which they were originated. Occasionally, academic or health authorities do not reexamine them because they come from center of undisputed prestige and carry economic incentives, which stimulate research in the host country. Clinical trials are not always beneficial to local communities, since they sometimes lead to the development of products of high market value unaffordable for them. The practice of “safari research, in which a group of experts from a developed country goes to an under developed one to get data since alright to some researches in the host country who may benefit from the prestige unfunding imply in the collaboration. Publication practices do not always demand explicit mention of the procedures for recluting volunteers, the way samples where configured, risks involved in some procedures or potential conflict of interests\(^{13}\).

Listing some particular features of the Latin American and Caribbean context for human subject research does not imply that HVE can solve the problems involved. However, they do deserve attention within the framework of the technical cooperation in health.

Proposed lines of action include among others, following actions:
- Increasing public attention to bioethical topics thorough public diffusion, their introduction to cleanse programs of studies and training of professionals associated with biomedical and psychosocial research.
- Diffusion of declarations, agreements, and codes about technoscientific research, health and education.
- Advising legislators, planners, opinion leaders and academic authorities about appropriate resources of information, comparative studies, and decision procedures in fomenting research and analysis of human rights.

\(^{13}\) Analysis must include an elaboration of the differences between health care and biomedical research. Medical professionals do not always clearly differentiate between the roles of the clinician and the researcher and their training leads them to give precedence to the first over the second, introducing a confusion in terms of the therapeutic privilege and patient consent. HBE will have to study the social roles and the current status of health professions in the Region.
- Institutional services in public and private context for the implementation of regulation testing processes of the scientific practice valid for the technosciences group.

- Constant testing of “ethics climate” prevailing in the social processes related to science, technology and their applications. For a long – term, “ethical sustainability” of research and the “moral vulnerability” of the countries of the continent will be concepts properly sustained for empirical reflection and grounds.

Certainly, these tasks are complementary to those, which HBI undertakes in the clinical and managerial areas. As far as health services is concerned, both priority settings and the establishments of mechanisms guarantying users accessibility and relationships between health practitioners and clients are susceptible of analysis and demand decision making in form by bioethical principles. It should not be forgotten that PAHO has made equity and panamericanism to of its most important conceptual axes for the formulation of its actions lines.

In all the areas in which it operates, HBI acts mediating between those who produce information, those who articulate information into knowledge (organized information with social values) and those who use, or apply them. It does not constitute an instance for judging practices or persons and it should nor be considered a reservoir of moral norm. Its activities are performed within the framework provided by the strategic and programmatic orientations formulated by PAHO for the next years.
ANEXO 1:
ENCUESTA A ORGANIZACIONES NACIONALES DE CIENCIAS Y TECNOLOGIA (ONCYT) DE AMERICA LATINA Y EL CARIBE

Cuestionario:

1. ¿Cuenta su Organización con un Comité de Etica? qué evalúe los protocolos de investigación o experimentación que le son presentados?

2. ¿Cuenta su Organización con un Comité de Etica (puede ser el mismo anterior) qué controle el desarrollo de las investigaciones?

3. ¿Cuenta su Organización con un Comité de Etica (puede ser el mismo anterior) qué conozca los resultados finales de las investigaciones?

4. Si su organización no dispone de Comité de Etica en alguna(s) de las etapas anteriores, ¿de qué forma se evalúa y/o controla las investigaciones?

5. Si su Organización cuenta con Comité de Etica:

   5.1. ¿Cómo está compuesto? (para cada integrante, por favor señalar: identificación, profesión, cargo, calificación científica y ética, si corresponde).

   5.2. ¿En qué fecha y a través de qué resolución (administrativa, legal) fue creado?

   5.3. ¿Dispone de actas de las reuniones que realiza?

   5.4. ¿Cuántos trabajos científicos ha evaluado en los últimos cinco años? (mencione sus títulos por favor).

   5.5. ¿Cuáles han sido las principales dificultades que ha encontrado en su funcionamiento?

   5.6. ¿Qué requeriría para hacer mejor su labor?

6. ¿Existen trabajos sobre Etica o Bioética que hayan sido financiados por su Organización? (si la respuesta es afirmativa, por favor mencione sus títulos y autores).

7. ¿Tiene su Organización vínculos con otras entidades que evalúen éticamente investigaciones científicas en seres humanos (Universidades, Comités de Etica autónomos, instituciones públicas y/o privadas de financiamiento de proyectos, etc.)? Si su respuesta es afirmativa, por favor señálelas, dando referencias de personas responsables y dirección postal (e-mail, fax, correo, teléfono, según le sea posible).
SURVEY FOR NATIONAL ORGANIZATIONS OF SCIENCE AND TECHNOLOGY
OF LATIN AMERICA AND THE CARIBBEAN (cont.)

Questionnaire:

1. Does your Organization have an Ethics Committee, for the evaluation of clinical research or experimentation? Is there compulsory submission to such a body in the approval process?

2. Does your Organization have an Ethics Committee (might be the same one) to supervise the development of research work?

3. Does your Organization have an Ethics Committee (might be the same one) which follows up on the final results of research work?

4. If your Organization does not have an Ethics Committee to act in one or more of the previous stages, how do you evaluate and/or control ethical aspects of research?

5. If you Organization does have an Ethics Committee:
   
   5.1 Membership and structure? (for each member, please indicate the following: identification, profession, position, scientific and ethic qualifications, if suitable).
   
   5.2 Date and legal procedure of creation.
   
   5.3 Record-keeping of meetings and resolutions.
   
   5.4 How many scientific projects have been evaluated during the last five years? (please mention their headings).
   
   5.5 Which are the main difficulties you have encountered in your operation?
   
   5.6 What would you need in order to accomplish a better work?

6. Are there any Ethics or Bioethics Studies financed by your Organization?

7. Does your Organization have connections with other organizations, which evaluate scientific research in human beings from the ethical point of view? (Universities, autonomous Ethic Committees, public and/or private project financing institutions, etc). If your answer is yes, please specify them, including references of responsible persons and postal address (e-mail, fax, post-office mail, telephone, if possible).
## ANNEX 2

### Table Summarizing Responses to ONCYT Survey

<table>
<thead>
<tr>
<th>Country</th>
<th>Agency</th>
<th>Date received</th>
<th>Committee proper</th>
<th>Observations</th>
</tr>
</thead>
</table>
| Honduras | Consejo de Ciencia y Tecnología                                        | 8/03/99       | No               | Integrates Bioethics Commission in PAHO Field Office in Honduras  
Member: Mr. Nancy Larra Smart, Coordinator of Projects and International Management                                                                                                                   |
<p>| Canada   | Conseil de la Science et de la technologie                            | 5/03/99       | No               | Is not involved in ethical review. Consultation forwarded to FRSQ (Fonds de la recherche en santé du Québec (the 29/01/99))                                                                               |
| Canada   | Fonds de la Recherche en Santé (Québec)                               | 5/03/99       | No               | In accordance with Canadian law, report and informed consent form required by independent Ethical Review Committee. Has Ethical Advisory Committee for research involving human beings. |
| Barbados | National Council for Science and Technology (NCST)                    | 4/03/99       | No               | NCST not involved in research involving ethical considerations.                                                                                                                                              |
| Ecuador  | Fundación para la Ciencia y la Tecnología (FUNDACYT)                  | 26/01/99      | No               | Interested in information and assistance to create one. The UNESCO Office in Ecuador promoting formation of an Ethical Review Committee.                                                                  |
| Venezuela| Consejo Nacional de Investigaciones Científicas y Tecnológicas (CONICIT)| 23/02/99      | No               | Ethics Commission in formation phase. Current projects evaluated through ad hoc commissions. Have Code of Bioethics and Safety, also used by the Scientific Research Institute of Venezuela (IVIC) |
| Panamá   | Secretaría Nacional de Ciencias, Tecnología e Investigación (SENACYT)  | 9/02/99       | No               | Ad hoc approval of some projects by Ministry. Contacts with National Institutes of Health, USA.                                                                                                             |
| Guatemala| Consejo Nacional de Ciencia y Tecnología (CONCYT)                     | 9/03/99       | No               | Projects do not undergo ethical review. Group of consultants periodically evaluates projects from technical standpoint. Did Mr. Julieta de Ariza attend Bioethics meeting in Santiago and then give talk to Health Commission? |
| Colombia | COLCIENCIAS                                                            | 11/03/99      | No               | COLCIENCIAS requires that all projects involving human subjects be certified by corresponding institutional Ethical Review Committee.                                                                         |</p>
<table>
<thead>
<tr>
<th>Country</th>
<th>Organization/Section</th>
<th>Date</th>
<th>Approval</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costa Rica</td>
<td>Consejo Nacional para Investigaciones Científicas y Tecnológicas (CONICIT)</td>
<td>10/03/99</td>
<td>No</td>
<td>Supervision of Ethical Review Committees (public &amp; private) carried out by National Research Council in Health, assigned to Ministry of Health. Every project involving human beings should have approval of Ethical-Scientific Committee, duly certified (Article 6 of Regulation, Executive Decree Nº 27, 349-S of 13 October 1998). CONICIT requires that every project financed have approval of respective Ethical-Scientific Committee.</td>
</tr>
<tr>
<td>Chile</td>
<td>FONDECYT</td>
<td>12/03/99</td>
<td>No</td>
<td>Every project involving studies on human beings should include a report of the Ethical Review Committee of the sponsoring institution and a letter of consent given to patients integrated into the study.</td>
</tr>
<tr>
<td>Bolivia</td>
<td>Viceministerio de Educación Superior, Ciencia y Tecnología (CONACYT)</td>
<td>11/03/99</td>
<td>No</td>
<td>Apparently, the Departmental Medical School of La Paz intervenes sporadically in the ethical review of research projects.</td>
</tr>
<tr>
<td>Cuba</td>
<td>Secretaria de Investigación dependiente del Ministerio de Salud</td>
<td>18/03/99</td>
<td>Yes</td>
<td>There exists a National Commission of Ethics that reviews all research projects involving human beings presented in the country. They attach the Constitution of the Commission.</td>
</tr>
<tr>
<td>Jamaica</td>
<td>National Commission on Science &amp; Technology (NCST)</td>
<td>23/03/99</td>
<td>No</td>
<td>Research projects undergo ethical review by the Ethical Committee of the School of Medicine of the University of West Indies and the University Hospital of the West Indies (UWI &amp; UHWI Ethical Committee) that have existed since the 1980s. Projects evaluated over the last five years: 65. They furthermore attach the Constitution of the Committee and the titles of the projects reviewed.</td>
</tr>
<tr>
<td>Peru</td>
<td>Consejo Nacional de Ciencia y Tecnología (CONCYTEC-PERU)</td>
<td>24/03/99</td>
<td>No</td>
<td>A favorable report has been requested from the Ethical Review Committee of the institution where the study is planned. In transnational projects, acceptance from the Ministry of Health is required, and review has been requested from the Ethics Commission of the Medical School of Peru.</td>
</tr>
<tr>
<td>Uruguay</td>
<td>Consejo Nacional de Investigaciones Científicas y Técnicas (CONICYT)</td>
<td>24/03/99</td>
<td>No</td>
<td>Every research project involving human beings should include a report of the Ethics Committee of the sponsoring institution and the informed consent form.</td>
</tr>
<tr>
<td>Argentina</td>
<td>Consejo Nacional de Investigaciones Científicas y Técnicas (CONICET)</td>
<td>29/03/99</td>
<td>No</td>
<td>Has an Advisory Commission of Biological Sciences and Health. Regulated by the Evaluation and Accreditation System (Resolution 55/99) in their Article 2°, 5; must “take into account the ethical considerations of the development of Biotechnology and the Health Sciences.” Therefore requires favorable report of Ethics Committee of the institution where the principal investigator is accredited, requires informed consent proceedings.</td>
</tr>
<tr>
<td>Mexico</td>
<td>Consejo Nacional de Ciencia y Tecnología (CONACYT)</td>
<td>8/04/99</td>
<td>No</td>
<td>The National Program of Science and Technology 1995-2000 establishes approval by an independent Ethics Committee for research projects involving human beings. The Council (through the Deputy Director’s Office of Scientific Research) reviews the projects in accordance with rules of procedure.</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>No se dispone de información por vía WEB ni OPS</td>
<td>9/04/99</td>
<td>No</td>
<td>By personal report (Dr. Perales) research projects are reviewed by the universities (and their respective Ethics Committees) and government grants funds. The directives used are those that established United States law.</td>
</tr>
<tr>
<td>Country</td>
<td>Governmental Body</td>
<td>Action</td>
<td>Contact Information</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Brazil</td>
<td>Coselho Nacional de Desenvolvimento Científico y Tecnologico (CNPq/RNP)</td>
<td>16/04/99 No</td>
<td>The law establishes ethical guidelines for research involving humans. Federal and National Councils supervise these. Favorable report required from independent Ethics Committee, project reviewed by Advisory Commission of National Board.</td>
<td></td>
</tr>
<tr>
<td>El Salvador</td>
<td>Consejo Nacional de Ciencia y Tecnologia (CONACYT)</td>
<td>Did not answer</td>
<td>Does not have website or e-mail. PAHO does not have information about this.</td>
<td></td>
</tr>
<tr>
<td>Paraguay</td>
<td>Instituto Nacional de Tecnologia y Normalizacion</td>
<td>Did not answer</td>
<td>Does not have website or e-mail. PAHO does not have information about this.</td>
<td></td>
</tr>
<tr>
<td>Trinidad and Tobago</td>
<td>Sent to National Institute of Higher Education, Research, Science and Technology (NIHERST)</td>
<td>Did not answer</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>Under U.S. ONCYT.</td>
<td>Did not answer</td>
<td>Organization based on United States legislation.</td>
<td></td>
</tr>
<tr>
<td>Belize</td>
<td>Not among ONCYT. No survey sent to them.</td>
<td>--</td>
<td>--</td>
<td></td>
</tr>
<tr>
<td>Guyana, Suriname, and French Guiana</td>
<td>Not among ONCYT. No survey sent to them.</td>
<td>--</td>
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<td></td>
</tr>
<tr>
<td>Grenada, Antigua and Barbuda, Sta. Lucia, Dominica, Sn.Vicente and The Grenadines</td>
<td>Not among ONCYT. No survey sent to them.</td>
<td>--</td>
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<td></td>
</tr>
<tr>
<td>Haiti</td>
<td>Not among ONCYT. No survey sent to them.</td>
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</tbody>
</table>