

*Guide N.º 3*

# Educating Bioethics Committees



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# Educating Bioethics Committees



UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION  
DIVISION OF ETHICS OF SCIENCE AND TECHNOLOGY

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## EDUCATING BIOETHICS COMMITTEES

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# FOREWORD

The Universal Declaration on Bioethics and Human Rights was adopted by acclamation on 19 October 2005, in Paris, at the 33<sup>rd</sup> session of UNESCO's General Conference. It affirms 'that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms'. The Declaration is an offshoot of UNESCO's Constitution, adopted on 16 November 1945, as well as the Universal Declaration of Human Rights, approved on 10 December 1948, and other declarations.

The primary aim of the Declaration is 'to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics'. Societies have to interpret and specify the precepts of bioethical norms and principles based upon both the morally significant diversity of human experience and the fundamental moral values shared by all cultures. The Declaration does not presume bioethicists to be watchdogs protecting the boundaries of morality in the health care and research context; rather, they facilitate and articulate reflection and interpretation, and are dedicated to offering a coherent account of both our significant diversity and our common morality in a world of rapidly innovative discoveries in the life sciences and biotechnology.

In this Declaration, UNESCO, on the basis of the drafts developed by the International Bioethics Committee, has identified 'universal principles based on shared ethical values to guide scientific and technological development and social transformation' and aims to reconcile the unchanging principles of human rights with constantly evolving applications of science and technology. The Declaration challenges bioethicists formally to consider and argue for adopting a broad human rights framework, to defend by sound argument a human rights foundation for bioethics, and thereby to question the soundness of its original foundation – the dogma of individual autonomy as self-determination, the worship of technology and unbridled *laissez faire* economics – and thereby advocate a new international consensus.

Among these general principles – stated in the Declaration's 28 Articles that are intended to 'provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment' – Articles 3 to 17 specifically, but broadly, outline moral principles, and signal the importance of addressing contemporary bioethical dilemmas and moral controversies, including some which may prove intractable.

A principal objective of this Declaration is to underscore UNESCO's acknowledgement of moral choices that arise from recent advances in the life sciences and biotechnology, and not only particular bioethical dilemmas facing sick and dying patients, physician-scientist researchers, those who participate in scientific and clinical research trials, and members of Bioethics Committees. The Declaration also stresses ethical decisions by individuals and families, vulnerable populations, culturally diverse indigenous and local communities, and specifically governments of UNESCO's Member States.

Article 23 of the Declaration – Bioethics Education, Training and Information – is specifically germane to *Guide No. 3*. It affirms that ‘States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics’. This *Guide*, like *Guides 1* and *2*, is specifically intended to foster bioethics education by providing support to present and future chairpersons and members of Bioethics Committees as they initiate and continue to pursue their bioethics education. This is an open-ended process, since novel bioethical issues, dilemmas, patients’ cases and cases of scientific misconduct continue to emerge almost daily in various Member States.

UNESCO’s Division of Ethics of Science and Technology can offer guidance, advice and consultation with respect to establishing Bioethics Committees at the national, regional and local levels of government, as described in *Guide 1*. *Guide 2* explores the internal working procedures and policies of four forms of Bioethics Committees:

1. Policy-Making and/or Advisory Committees, intended to establish sound science and health policies for Member States’ citizens (e.g. the public’s health, well-being and rights).
2. Health-Professional Association Committees, although organized to promote their members’ professional interests, also establish sound professional practices for patient-centred care (e.g. physicians’ associations, nurses’ associations, pharmacists’ associations).
3. Health care / Hospital Ethics Committees, intended to improve patient-centred care (e.g. hospitals, out-patient clinics, long-term care institutions, hospices).
4. Research Ethics Committees, intended to protect human research participants while acquiring generalizable biological, biomedical, behavioural and epidemiological knowledge (e.g. pharmaceuticals, vaccines, surgical techniques, implantable devices), and to encourage research integrity and the responsible conduct of research.

Once Bioethics Committees are established, have clarified their goals, and adopted their internal procedures and policies, they can begin to carry out their functions. This task, however, imposes a duty of long-term education that, in time, may lead them to modify these goals, procedures and policies to take into account what they have learned. As time passes, the committees’ focus on self-education may expand to educating colleagues in their institutions and eventually to fostering productive public debate and involvement.

To assist chairpersons and members to pursue these educational endeavours, and to realize the goal of compassionate understanding and decision-making in the face of complex bioethical issues and dilemmas, we offer *Educating Bioethics Committees*.

We are grateful to Emeritus Professor Stuart F. Spicker for his assistance in preparing and developing this *Guide*.

Henk ten Have  
Director  
Division of Ethics of Science and Technology  
UNESCO

# INTRODUCTION

The world of Bioethics Committees is ever changing, often with stunning speed and in unexpected directions. New scientific discoveries, new biotechnologies, new government policies and regulations, new judicial rulings, new international agreements, new professional attitudes, new societal norms and customs, and equally importantly, new bioethical dilemmas and arguments – changes come in a flood and on many fronts. There is a growing consensus that if committee members are to respond effectively to these changes, they must undertake long-term and increasingly intensive education. Moreover, there are practical as well as theoretical reasons for advocating education: it is far less threatening to members than requiring that they meet external, formal criteria in order to serve as Bioethics Committee members. Yet, members cannot effectively initiate this educational process unless they first consider the particular goals and functions of their committee. The purpose of any educational effort must be for the members to increase and improve their knowledge. The members of the four forms of Bioethics Committees should aim to increase and improve their knowledge of bioethics. If they continue to pursue this goal, they will be in a better position to fulfil the committees' objectives in light of their particular mandates.

Individual members may choose to specialize in specific areas, on the theory that specialization of function and division of labour is the most sensible way for the committee to function. Or individual members may conclude that they are all obligated to participate actively in all committee decisions, and that specialization would leave them too passive in many areas. Whichever approach the individual member selects, his or her education must be serious – major consequences will follow from committee actions – and never ending – for change will never cease but on the contrary is likely to increase in velocity. Education, therefore, emerges as a fundamental responsibility of committee members, one that must be initiated and systematically pursued before a number of substantive tasks may be considered.

Successful Bioethics Committees usually begin the process of education slowly, introducing the process of self-education when they first begin to convene as a group. Bioethics is complex and multifaceted, drawing on philosophy and law as well as science and medicine. Most committee members will lack special training and experience in bioethics, and though they typically have significant expertise in other fields, must be willing to devote some time to this multi-disciplinary field. This is particularly the case with respect to new members, who should be provided with (or given online access to) carefully selected reading material prior to participating in committee meetings, since they are expected actively to participate in the educational sessions as well as the standard sessions.

New members may require a few training sessions to introduce them to bioethics, sessions which do not require the presence of experienced members who might find attending them an imposition. These introductory-level sessions will serve to familiarize new members with important topics for their particular form of committee, and at least introduce them to ethical decision-making in health care, broadly conceived. Members should be informed that some bioethical issues will be germane to

members of all four forms of Bioethics Committees, while others will be of interest only to the members of a particular form. For instance, members of Research Ethics Committees do not usually become involved in bioethical issues that confront individual patients or their families, for this is reserved for Health care or Hospital Ethics Committees whose members are mostly clinicians and non-scientists, though lay persons are also among the members. Indeed, in recent years there has been a significant increase in lay membership in all forms of Bioethics Committees; during the next decade, owing to the increasing public demand for transparency with respect to persons whose work directly affects the public, it is likely that more lay members will be invited to join Bioethics Committees.

Furthermore, chairpersons and members who are bioethicists should not assume that other members will share a common understanding of bioethics or what constitutes a bioethical dilemma rather than an issue in health law, since law and ethics are often conflated in the minds of the general public. Committee education, then, should also formally include the analysis of relevant legal concepts and important legal cases. Committees acting with a sound legal grasp of the issues would also reduce the likelihood of subsequent civil or criminal court involvement. However, new committee members will require assistance in identifying and formulating bioethical and health law issues. This may necessitate some discussion of what normally falls under rhetoric or sophistry, an art usually mastered by attorneys determined to win by their advocacy.

When new members are added to a Bioethics Committee, it may be helpful to provide them with minutes of past meetings and other information that reflect the prior work of the committee, especially if it has been established for some time. It is also important for those conducting the educational sessions of new members to make clear what is beyond the committee's purview. New members must understand, for example, that Bioethics Committees by and large have no legal authority or function, though they may have social or moral authority. It has been observed that committee members usually share and act upon similar values and norms when they live within a particular culture.

Individual self-education, in some contexts, might include taking a short course in bioethics, perhaps offered by a local education institution, and the Bioethics Committee's chairperson may be able to secure funds to reimburse members for expenses they incur while pursuing such courses or seminars. As time passes, Bioethics Committees tend to devote a portion of their time to case studies – present and retrospective, actual and hypothetical – and on occasion they may even invite outside speakers to offer presentations to or to provide testimony before the committee. It is important, however, to note that the members themselves are a significant source of information, and they can learn from one another, each member accepting the role of peer educator. This, of course, requires the committee members to utilize a variety of pedagogical methods during their peer education efforts. Chairpersons would do well to take advantage of the scope of knowledge of the members and formalize this into specific educational sessions, each with a specific focus. This process can serve to enhance committee functioning, as the members come to understand one another better. In the end, members of Bioethics Committees should be able to look back and appreciate that they have developed not only ethical sensitivity but also critical thinking skills, and have learned effectively to formulate and resolve bioethical dilemmas that have arisen in clinical practice or while conducting life-science research.

Experience, in short, has refuted the old assumptions that life had sufficiently prepared members for their task or that their pre-existing moral and social values rendered them impervious to change, or that self-education by committees was at best redundant. Nearly all practising scientists and health professionals, who have been Bioethics Committee members, agree that bioethics education is essential to enable them to identify conflicts of values, increase their sensitivity to the perspectives of patients and research participants by reducing the gulf between researchers and participants, improve their understanding of their own values, deal more openly with bioethical dilemmas, offer better reasoned responses, and provide the context to explore more thoroughly the implications of different courses of action before taking action as a committee.

This guidebook is intended to assist the members of all four forms of Bioethics Committees to pursue their knowledge of the complex multi-disciplinary field of bioethics. It will provide examples and refer to useful educational resources. Section V (Suggested Topics for Educating Bioethics Committees) is articulated in Appendices I to IV that immediately follow. These topics have been selected to include the broad range of bioethical concepts, issues and dilemmas of interest to members of Bioethics Committees across UNESCO's Member States in various regions. Rather than provide extensive reading lists, many of which may soon become outdated, *this Guide* directs readers to various materials in pursuit of more intensive education in bioethics. The members of the four forms of committees are perhaps best served by being informed of materials accessible online and without cost. Various sources (see Appendix IV, International Bioethics Journals and Newsletters), as well as reading material which is accessible online (see Appendix V, International websites, and Appendix VI, UNESCO Publications), have been listed. This approach has been adopted so that a Bioethics Committee from any Member State, established at any level of government, may more easily pursue its members' interests and their increasingly intensive education, selecting and addressing specific topics it judges appropriate at any given time.

## Part I

### PROCEDURES FOR EDUCATING BIOETHICS COMMITTEE MEMBERS

At a practical level, Bioethics Committee education requires members to be informed prior to joining a committee that they are expected to continue the process of education – to be prepared to discuss problems and bioethical dilemmas that are likely to emerge and require group discussion. Members should be made aware of the distinction between *procedural* and *policy* issues, which serve to guide the committee’s activities (see *Guide No.2*), and *substantive* bioethical concepts, problems and dilemmas that constitute the field of bioethics and are likely to require the committee’s attention. Members should also be made aware that in the professional development of bioethics as a scientific discipline over the past few decades, a substantial body of knowledge has emerged. Such knowledge not only provides a global frame of reference for bioethical decision-making, it also provides information, analysis and clarification that will be useful for interpreting and discussing cases, problems and policies in specific cultural, religious and political contexts.

Committee education requires each committee to adopt specific procedures that support this undertaking. Committees will be in different stages of development. They will also have variable and often limited resources. This will imply that a longer-term perspective is necessary and that a stepwise approach to educate committee members in the field of bioethics is unavoidable.

A committee – of whatever form – might consider the following steps.

#### 1. SELECTING AND ACQUIRING EDUCATIONAL RESOURCES AND MATERIAL

The chairperson should request the committee’s secretariat or staff (a) to monitor and bring to the committee’s attention important new developments revealed in the scientific literature, relevant bioethics journals and newsletters (see Appendix IV), plus the mass media; (b) prepare a briefing book to register these and other foundational bioethical topics and issues; (c) create user-friendly, online systems that offer access to a wide variety of material (see Appendices V and VI); (d) if not locally available, establish an accessible, modest library that maintains an updated bibliography of relevant readings and audiovisual recordings (as well as an archive of earlier publications); and (e) create a permanent resource centre easily accessed by the chairperson and members prior to and following all sessions the committee decides to devote to its bioethics education.

If a committee has the support of a secretariat and access to a science and technology office or an office of health law, these support services should provide the chairperson and the members with invaluable current material pertinent to the committee’s mandate and agendas.

To facilitate this first step, the UNESCO Global Ethics Observatory<sup>1</sup> might be a helpful resource. Other support might be provided through creating regional networks of bioethics committees with national or regional documentation centres available for all committees in the network.

<sup>1</sup> <http://www.unesco.org/shs/ethics.geobs>

## **2. READING, STUDYING AND PREPARING FOR COMMITTEE MEETINGS**

The chairperson, and especially the members who are experts in bioethics, should devote a considerable amount of time studying the subject that the committee is currently reviewing, and preparing materials to be assigned to other members. Over time, committee members – many of whom have had a pre-existing interest in bioethics and may already be members of bioethics organizations – tend to adapt their continuing education to the work of the committee: they begin to attend additional bioethics conferences and participate in and take advantage of other opportunities for continuing education.

If a Bioethics Committee can obtain funding, it may decide to sponsor and organize two- or three-day conferences, and enable its members to attend week-long, intensive seminars and courses on bioethical topics, issues and dilemmas. Individual members should also be supported to attend professional conferences that have a direct bearing on the committee's continuing education in bioethics. A member who attends a conference should be expected to report what he or she learned to the full committee in order to enhance the education of all the members.

## **3. REPORTING AND DISCUSSING IMPORTANT AND RELEVANT BIOETHICS LITERATURE**

Committee members usually have ample opportunity to share their knowledge, particularly knowledge acquired from reading bioethics journals, scientific reports, special documents, media presentations, Internet and online documents, and correspondence among themselves. The chairperson should accept the responsibility to signal and make available to members significant articles and newsletters that have appeared in the most recent bioethics publications. If chairpersons or committee secretaries do not report these sources of relevant information, members cannot be expected to learn from them.

During committee meetings individual members should be encouraged to offer brief presentations, supplemented by handouts and other inexpensive pedagogical techniques.

Committees may also elect to role-play and to discuss purely hypothetical cases or research proposals, not only those formally submitted to the committee for its advice, recommendations or decisions. This technique is especially useful during a committee's initial year, since many members prefer to pursue self-education prior to participating in discussions of actual cases or protocols that may well require formal action.

## **4. INVITING EXPERTS AND SPEAKERS**

The committee may invite speakers to offer testimony and presentations at selected sessions (some of which may be open to the public). The professional credentials of each speaker should have been submitted some time in advance of his or her presentation and then retained in the committee's archives. The chairperson may assign a committee member to guide discussion of the speaker's presentation. But, in any case, the meeting should include time for committee members to comment, raise questions for the speaker and stimulate discussion. Following some education sessions,

the speaker should be asked to submit a formal paper on the topic of the presentation (which the committee may decide to include in one of its future publications). The chairperson or a member of the committee should remain in contact with each speaker in case members decide to invite the speaker back to offer additional presentations or testimony. During this interval, members should be made aware of any current research that has a bearing on procedural or substantive issues that pertain to the committee's work, and have been made explicit by a guest speaker. The committee may also invite public comment – oral and written – in order to solicit viewpoints not represented by the committee's members.

## **5. CONDUCTING MORE INTENSIVE FORMAL EDUCATION SESSIONS**

The more intensive step in the Bioethics Committee education process may be divided into two parts: (1) general principles that all members of Bioethics Committees need to know (see Part II), and (2) specific topics that the committee members of each of the four forms of Bioethics Committees need to know (see Part III).

### **STEPS IN EDUCATING BIOETHICS COMMITTEES**

- 1.** collect basic educational resources
- 2.** individual capacity-building
- 3.** discuss relevant material
- 4.** invite experts and speakers
- 5.** intensive education sessions

## Part I

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### STEPS IN EDUCATING BIOETHICS COMMITTEES

1. collect basic educational resources
2. individual capacity-building
3. discuss relevant material
4. invite experts and speakers
5. intensive education sessions

## Part II

### WHAT ALL BIOETHICS COMMITTEE MEMBERS NEED TO KNOW: GENERAL PRINCIPLES

Bioethicists generally hold the view that all committee members – life scientists, health professionals, specialists in health law, philosophers, theologians, social and behavioural scientists, social workers, institutional risk managers, lay members – need to be acquainted with the more influential ethical theories, virtually all of which respond to the question: ‘How ought I to act?’ or ‘How ought we to act?’ Teleological theories, deontological theories, consequentialist theories, casuistry (case-based analysis), virtue theory and a few others, have dominated ethical reflection in all civilizations. In the mid-twentieth century some of these ethical theories re-emerged (a) in the context of health care decision-making, followed by action, and (b) in the acquisition, possession and application of new knowledge and the development of various biotechnologies.

UNESCO’s Universal Declaration on Bioethics and Human Rights is particularly relevant to the goals and work of all Bioethics Committees. Article 19 – Ethics Committees – states: ‘Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level [of government] in order to: ... (iv) foster debate, education, and public awareness of, and engagement in, bioethics’. Furthermore, fifteen of the Declaration’s 28 Articles (3 to 17), the Principles, are intended to ‘provide a universal framework’ to guide UNESCO’s Member States ‘in the formulation of their legislation, policies or other instruments in the field of bioethics’.

In addition to these goals, however, the Declaration boldly challenges and rejects the prevailing, popular moral theory known as conventional, cultural, or ethical relativism – a form of ethical scepticism – that goes far beyond the claim (which virtually no one disputes) that different social groups often have different values or ethical opinions. Rather, the conventional ethical relativist claims that moral principles cannot be demonstrated to be valid for everyone across all cultures and societies, that there is no unique rational or justified method in ethics, and that, therefore, conflicting ethical opinions are equally valid. That is, the search for common moral ground across all cultures and societies is in principle doomed to fail because there is no overarching set of norms, only diversity in both the secular and non-secular worlds.

Put another way, the ethical relativist is not merely saying that ‘Nothing is right or wrong!’ or ‘Some things are both right and wrong!’ The ethical relativist is saying that some ethical opinions are not more valid than some other ethical opinions that conflict with them; that conflicting ethical opinions are equally valid even when both opinions are about the same subject. The ethical relativist maintains that actions are morally right if the society or culture in which they occur approves them and morally wrong if it disapproves them.

The UNESCO Declaration, however, asserts that actions can be morally right yet disapproved by a society or culture, or they can be morally wrong yet approved by a society or culture.

Consider the Declaration's bioethical Principles (Articles 3 to17):

### **ARTICLE 3 – HUMAN DIGNITY AND HUMAN RIGHTS**

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interest and welfare of the individual should have priority over the sole interest of science or society. [NOTE: The word 'should' is used here prudentially and is not a synonym for 'must', i.e. a society's interest may *occasionally* take priority over the interest of the individual; an individual's interest does *not* have absolute priority over all societal interests all of the time.]

### **ARTICLE 4 – BENEFIT AND HARM**

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized. [NOTE: The first use of the word 'should' is prudential and is not a synonym for 'must', i.e. asserting that benefits to participants *should be maximized* does not entail that benefits to participants must always be maximized; the second use of 'should', however, is normative and does require that any possible harm to individuals must be minimized.]

### **ARTICLE 5 – AUTONOMY AND INDIVIDUAL RESPONSIBILITY**

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

### **ARTICLE 6 – CONSENT**

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include the modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration...and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

#### **ARTICLE 7 – PERSONS WITHOUT CAPACITY TO CONSENT**

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

1. authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

2. research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

#### **ARTICLE 8 – RESPECT FOR HUMAN VULNERABILITY AND PERSONAL INTEGRITY**

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

#### **ARTICLE 9 – PRIVACY AND CONFIDENTIALITY**

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

#### **ARTICLE 10 – EQUALITY, JUSTICE AND EQUITY**

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

#### **ARTICLE 11 – NON-DISCRIMINATION AND NON-STIGMATIZATION**

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

## **ARTICLE 12 – RESPECT FOR CULTURAL DIVERSITY AND PLURALISM**

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in the Declaration, or to limit their scope.

## **ARTICLE 13 – SOLIDARITY AND COOPERATION**

Solidarity among human beings and international cooperation towards that end are to be encouraged.

## **ARTICLE 14 – SOCIAL RESPONSIBILITY AND HEALTH**

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction or race, religion, political belief, economic or social condition, progress in science and technology should advance:

- (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
- (b) access to adequate nutrition and water;
- (c) improvement of living conditions and the environment;
- (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
- (e) reduction of poverty and illiteracy.

## **ARTICLE 15 – SHARING OF BENEFITS**

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
- (b) access to quality health care;
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
- (d) support for health services;
- (e) access to scientific and technological knowledge;
- (f) capacity-building facilities for research purposes; and
- (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

**ARTICLE 16 – PROTECTING FUTURE GENERATIONS**

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

**ARTICLE 17 – PROTECTION OF THE ENVIRONMENT, THE BIOSPHERE AND BIODIVERSITY**

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

(See appendix VI for the link to the full text of the Declaration)

## Part III

### WHAT MEMBERS OF BIOETHICS COMMITTEES NEED TO KNOW: BIOETHICAL DILEMMAS

Before considering typical examples of bioethical dilemmas that the four forms of Bioethics Committees could conceivably confront, the reader is reminded that the term ‘dilemma’ is a technical one; it refers to a form of argument in which two premises lead to a conclusion (see *Guide 1*). It is, of course, a commonly used word to mean that one must choose between two more or less equally unpleasant alternatives, though sometimes the alternatives may be acceptable, but this is not usually the case in the health care context. Formulating a dilemma usually forces a committee into an either/or choice that it would be best to avoid entirely. This requires serious deliberation, which should serve to clarify the complex situation. A compromise may be the best outcome a committee can achieve.

Although policy makers, scientist-researchers, research participants, patients – their families and their proxies – and even health care institutions, may act as moral agents at various times, Bioethics Committees confront moral dilemmas that require careful thought, in order to find ways to avoid the so-called ‘horns’ of a dilemma (the two negative alternatives). This is usually followed by recommendations that call for specific action to be taken that reflect the committee’s consensus. In the end, the committee hopes to avoid the extreme, unpleasant alternatives that it initially confronted.

Since the four forms of Bioethics Committees have different functions, purposes, procedures and internal policies, they tend to address quite different concerns.

#### 1. POLICY-MAKING AND/OR ADVISORY BIOETHICS COMMITTEES

Policy-making and/or Advisory Bioethics Committees at the national level of government assist in developing or reinforcing the bioethics infrastructure in their countries, for example through advising the government in regard to legislation. Each committee’s members are usually appointed by the government and are thought to reflect the values, perspectives, and policy preferences of the population. The members are not supposed to act like independent judges, but they are expert advisers who can bring their experience and technical expertise to bear on bioethical questions and dilemmas. In this way, they help to make the most adequate policy choices in regard to bioethical issues.

The committee members in addition may be charged with educating the public and stimulating widespread discussion of bioethical issues. Thus, they may contribute to placing an issue on the social or political agenda or defining the problem or validating a vocabulary or mode of discourse.

Occasionally, these committees will become entangled in political controversies, and critics may charge that this undermines the non-political image on which their authority rests. But the committees frequently conclude that they can avoid controversy only by avoiding important, highly visible subjects, that is, by embracing timidity. What is the point of having authority, they ask, if there is a refusal to

exercise it? This is important if the committees hope to obtain and retain the confidence and respect of life scientists, health professionals, and the general public.

### **1.1 Substantive bioethical issues of importance to citizens of Member States**

Policy-making and/or Advisory Bioethics Committees, since they usually are established at the national level of government, should represent a variety of views on significant bioethical issues. Committees in a number of Member States have addressed controversial bioethical issues that reflect competing moral positions by the public, where life lived experientially encounters the results of biotechnology and life studied scientifically.

#### **CONTROVERSIAL BIOETHICAL ISSUES: EVERYONE'S BUSINESS**

1. Human procreation – natural and artificial.
2. Commodifying human organs, tissues and cells – selling and purchasing.
3. Unrestrained scientific freedom leading to innovations that may harm future generations.
4. Used and misused biotechnologies to serve non-beneficial ends.
5. Genetic enhancements (e.g. the desire for 'better children', 'superior performance', 'satisfied psyches devoid of painful memories' and 'ageless, ever youthful bodies') – affordability, access and justice.
6. Complexities overseeing and regulating the development and uses of new biotechnologies, as well as scientists' and health professionals' self-regulation and monitoring.
7. Implications of limiting biological research.
8. Providing equitable access to the use and benefits of new biotechnologies.
9. Questioning where humanity newly-empowered by biotechnologies is heading beyond curing disease, relieving suffering and restoring health.

### **1.2 An illustrative example at the national level of government**

#### **Personal genetic information: is it confidential, and if so, from whom should it be protected?**

As genomic medicine and the science of genetics advance, they will prove not only highly prognostic regarding an individual's health, but will emulate the natural sciences in their quest to predict future states of affairs. As time passes, and additional medical conditions are linked to genetic-based predispositions, it will become increasingly difficult to distinguish genetic data from other medical information. In order to guide decision-making and policy development at global level, in 2003 the Member States of UNESCO adopted the *International Declaration on Human Genetic Data*. This Declaration provides principles and provision for the collection, processing, use and storage of human genetic data.

The incremental sophistication of the science of genetics and genomic medicine has led to a series of bioethical problems, only one of which shall be discussed as an example of the tasks typically confronted by Policy-making and Advisory Bioethics Committees at the national level of government.

Personal genetic information may well be of interest to a number of parties for commercial and other uses: (a) health and life insurance companies; (b) employers; (c) the criminal justice system; (d) the education system; (e) child adoption agencies; and (f) the military services.

Some nations have enacted legislation to protect individuals from discrimination. However, an insurance firm might maintain, for example, that it is in the business of risk management for its customers and that it needs genetic information to determine what these risks are. Otherwise, high or low risk persons will be classified incorrectly and forced to pay inappropriate premiums. If firms can ask an applicant's gender – a risk factor over which the individual has no control – why not his or her genetic profile? It may also be in the individual's interest to know his or her genetic profile to plan for the future or act to minimize risks. If insurers obtain the information, individuals will, too. Should the law counter all this, preferring ignorance to knowledge? To this, individuals reply that firms would refuse to sell premiums to persons with high risk genetic profiles, and that genetic inquiries are a threat to privacy that will sometimes inform a person of a prognosis that he or she would desperately not want to learn. As the genetic sciences advance, these fears will become even more pronounced. To what extent and under what conditions are insurers entitled to what kinds of genetic information?

### **A Bioethical Dilemma:**

**Premise 1-A** If a citizen's genetic information is made available to insurers, some will be denied coverage, or forced to pay high premiums, or have to forgo insurance; and

**Premise 1-B** if a citizen's genetic information remains unavailable to insurers, the insurers will misallocate risk and charge customers inappropriately.

**Premise 2** Either a citizen's genetic information is disclosed and available to insurers, or it is not.

**Conclusion** Either a citizen risks denial of coverage or higher premiums, or insurers misallocate risk and charge customers inappropriately.

Nor is the genetic profile controversy confined to health insurance. Employers may also desire this information, as they have a strong interest in a healthy workforce. Like insurers, employers may believe that this information is relevant (and not arbitrary) and therefore that they are entitled to obtain it. Employees, like insurance applicants, may fear that this genetic information could be used to their disadvantage and might find the demand for it an intrusion on their privacy. It is precisely for these reasons that the *International Declaration on Human Genetic Data* has formulated principles. However, in specific cases and circumstances these principles need to be weighed in order to reach a balanced and justifiable conclusion.

The particular dilemma stated above is only one example of the starting point for Policy-making and Advisory Bioethics Committees' deliberations at the national level of government.

## THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

This Declaration, adopted in 2003 during the 32<sup>nd</sup> General Conference of UNESCO includes the following Articles relevant to collection, processing, use and storage of human genetic data.

### Collection

- Art. 8: Consent
- Art. 9: Withdrawal of consent
- Art. 10: The right to decide whether or not to be informed about research results
- Art. 11: Genetic counselling
- Art. 12: Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings

### Processing

- Art. 13: Access
- Art. 14: Privacy and confidentiality
- Art. 15: Accuracy, reliability, quality and security

### Use

- Art. 16: Change of purpose
- Art. 17: Stored biological samples
- Art. 18: Circulation and international cooperation
- Art. 19: Sharing of benefits

### Storage

- Art. 20: Monitoring and management framework
- Art. 21: Destruction
- Art. 22: Cross-matching

(See appendix VI for the link to the full text of the Declaration)

## 2. HEALTH-PROFESSIONAL ASSOCIATIONS' BIOETHICS COMMITTEES

### 2.1 Substantive bioethical issues of importance to members of Health-Professional Associations

Health-Professional Associations' Bioethics Committees usually have mandates to produce for distribution to their members, not only newsletters but also extensive reports on meetings whose principal focus is a particular bioethical theme, problem or dilemma as well as to formulate ethical guidelines on medical practices.

A committee focus on pediatrics, for example, might address the following bioethical topics: Parental refusals to immunize their children; Genetic testing in paediatrics; Palliative care for children; Foetal therapy; Care of critically ill infants and children; Guidelines on foregoing (withholding and withdrawing) life-sustaining medical treatment for infants and children; Religious objections to medical care for children; and Organ transplantation for children and infants. To produce reports on these topics, some of which may lead to new practice policies, subcommittees of the Bioethics Committee usually convene for a number of daily sessions over the course of months; some of the sessions may be open to all members of the association. Invariably, the bioethics subcommittees soon discover that they

must consider a number of bioethical issues from a variety of perspectives, making their inquiry more complex than they might have forecast.

## **2.2 An illustrative example of importance to Health-Professional Associations**

### **An amended organ transplantation policy: should marginal organs be transplanted to compensate for the shortage of high quality organs?**

The transplantation of human organs – kidneys, bone marrow, pancreases, hearts, livers, lungs – has been increasing at a rapid rate since the discovery, around 1961, by Dr George H. Hitchings and others, of a powerful immunosuppressant drug treatment, azathioprine, as well as prednisone, that minimize organ rejection and greatly improve the survival of the recipients of unmatched graft transplants. For his accomplishments, Hitchings was awarded the Nobel Prize in Physiology or Medicine in 1988, almost thirty years later. His important work was preceded by equally important discoveries by clinicians, who were not only basic scientists. For example, Dr Joseph E. Murray performed the first human kidney transplant in 1954, and Dr E. Donnall Thomas performed bone marrow transplantation in 1956, though they did not share the Nobel Prize in Physiology or Medicine until 1990.

Since the inception of organ transplantation in the 1950s, the number of potential organ recipients has grown in virtually all Member States, generating an ever-increasing organ shortage of transplantable high quality cadaveric organs and living, non-cadaveric organs and tissues. Although many Member States offer organ transplantation, this procedure is simply unaffordable for most patients. Owing to the shortage of cadaveric organs and also to ensure high quality organs and better prognosis, in some cases such as kidney transplant, living donors are becoming preferred to cadaveric organs. At one time it was believed that it would not be too difficult to obtain kidneys from living, related donors, particularly in Member States with a large number of close-knit families, but this has not turned out to be the case for a number of reasons, including complex religious and social values.

A less known fact is that less-than-pristine, viable organs – dubbed ‘marginal’ – have increasingly been selected by transplant surgeons by applying so-called ‘extended or expanded criteria’. Organs are classified ‘marginal’ if retrieved from a deceased donor over 60 years of age, or one over 50 years of age with two of three characteristics – stroke, hypertension or abnormal kidney function. Simply because an organ is derived from an older donor, however, does not rule it out for transplantation. Indeed, kidney transplant surgeons advocate the use of donors over 60 years of age despite the presence of ‘renal senescence’.

Criteria other than age are of greater importance when concluding an organ is marginal: Is the donor an alcoholic? Is there cocaine in the blood? Did he or she suffer a chronic illness – hepatitis C, cancer, infectious diseases, diabetes, high blood pressure, or a rare disease? Did the donor have permanent tattoos that could exacerbate blood-borne diseases? Was the donor morbidly obese? Did he or she acquire a sexually transmitted disease? Did the donor suffer any lung disease due to smoking?

A potential recipient may not always participate in the crucial decision whether to accept a marginal organ. Should he or she be fully informed of the significance of receiving a marginal organ

when participating in the informed consent process? Indeed, should every potential recipient be so informed? Are there circumstances that warrant not informing a potential recipient that he or she is to receive a marginal organ, especially since transplantation has become the treatment of choice? What gives a sting to this question is that recipients are rarely considered eligible for a second transplant. If they have only one chance, they will surely want to spend it on a high quality organ.

Members of the transplant team also need to be fully cognizant of the physiological and psychological status of the potential recipient of a marginal organ, following the results of biopsy and histological scoring. At present, there is an immensely complex weighing of benefits and risk of harm in virtually all cases. Is the potential recipient sick enough to justify using any organ, even a truly marginal one, to try and save his or her life and give the patient only a few more years of life? Since the selection of marginal organs is a rather recent phenomenon, a good deal remains unknown, including the acquisition of sound statistical data on which transplant surgeons may comfortably rely; this in itself indicates the pressing need for further studies. Until they have been accomplished and the results thoroughly examined, transplant surgeons tend to adopt a straightforward utilitarian maxim: transplant the most extended – criteria organs into less critically ill patients and the healthiest organs into the sickest patients.

Some may advocate the contrary maxim because they view it as more equitable: transplant the most extended – criteria organs into the sickest patients and the healthiest organs into less critically ill patients.

It is possible to formulate a number of bioethical dilemmas in the context of the use of marginal organs – whether to permit the sale of organs from living donors, which is frequently addressed in the extant bioethics literature – but another seems paramount.

## A Bioethical Dilemma:

**Premise 1-A** If transplant surgeons, given the ever-present shortage of pristine organs, do not retrieve, select and transplant marginal organs (by applying ‘expanded’ or ‘extended’ criteria), then many more potential recipients will deteriorate and likely die, the deterioration extending into other bodily systems beyond the one targeted for transplant.

**Premise 1-B** If transplant surgeons, given the ever-present shortage of pristine organs, select and transplant marginal organs by applying ‘extended’ criteria, then some patients who receive marginal organs will perform poorer than those receiving pristine organs, and some of the marginal organs will fail, and these patients will be unable to secure a second transplant.

**Premise 2** Either surgeons do not transplant marginal organs or they do (i.e. they apply ‘extended’ criteria and no longer transplant only pristine organs).

**Conclusion** Either more potential recipients will deteriorate and probably die, the deterioration extending into other bodily systems beyond the one targeted for transplant, or very sick patients awaiting organs will probably not be eligible for a second transplant.

Members of Health-Professional Associations’ Bioethics Committees who may encounter dilemmas of this sort, and who are expected carefully to review all the scientific, clinical, legal and bioethical

features germane to the issue at hand – the use of marginal organs from virtually anyone – will require time to study the multi-disciplinary features and empirical evidence surrounding this relatively recent bioethical problem. The members of Bioethics Committees of Health-Professional Associations are usually expected to formulate practice policies, which establish a set of ethical and medical guidelines. At the very least, there should be consensus with respect to the informed consent process and its multiple features, since not all health professionals involved in organ transplantation agree with the utilitarian maxim noticed above; nor do they agree that all patients awaiting organs should be told as much as possible, i.e. that they will receive a marginal organ.

Finally, there is at present no international or professional authority charged with the task of formulating recommendations about what patients should be told, what kinds of organs should be used, and what policy should be adopted with respect to the increasing use of marginal organs to save additional lives through transplantation medicine.

### 3. HEALTH CARE / HOSPITAL ETHICS COMMITTEES

#### 3.1 Substantive bioethical issues of importance to patients, their families and practising health professionals

A perusal of bioethics literature and the extensive media coverage of bioethical issues in a large number of Member States reveals that the public is principally concerned with bioethical issues and dilemmas that emerge at (what one theologian called) ‘the edges of life’ – birth and death.

The public tends to understand bioethical issues and grasp various moral dilemmas by approaching these problems from various religious perspectives.

For example, bioethicists, clergy and members of Health care Ethics Committees in health care institutions are usually expected – on a daily basis – to engage patients, their families and a myriad of health care professionals in discussions of end-of-life issues, which quite often require taking decisions that have irreversible consequences – death. Imminent death may compel health professionals and the members of Health care Ethics Committees to engage patients and their families in discussions that require clarification of their religious beliefs. Unfortunately, bioethical, health law and religious concepts and questions are often not clearly distinguished and are conflated; this alone inhibits adequate understanding which may easily lead to unnecessary conflict among the parties involved in a particular patient’s case.

Health care Ethics Committees are often called upon precisely when such conflicts arise. However, discussions among health professionals, bioethicists and the lay public are best undertaken without recourse to formal ethical theories or bioethical principles, for this level of discussion might simply serve to alienate patients and their families, especially when they are experiencing a stressful period involving the serious illness or imminent death of a loved one – infant, child or adult. Moreover, infants’ and children’s wishes, as well as the preferences of many adults, are not always available; mental competency is lacking. Mental incapacity serves to limit bioethical discussions, and often requires the participation of patients’ proxies to speak on and participate in health care decisions on behalf of these patients, many of whom are *in extremis*. Again, this is usually the time to convene Health care Ethics Committees; they often serve as the platforms for such conflict resolution.

The bioethical discussions among health professionals, clergy and the public have, in the past, permitted deception – misleading patients and their families – but this is no longer acceptable; health professionals have become far more sensitive to the importance of truth-telling in their encounters with patients and their families.

In a number of Member States, patients and their families may legally refuse treatment (which is not the same as refusing care), but this does not mean that they may demand treatment, either; this would create an unwarranted burden for health professionals, to say the least.

Health professionals have, since the time of the Nuremberg Code, come to appreciate the importance of acquiring the informed consent of patients and their proxies. Acquiring permission is at the heart of informed consent; before attempting to do so, health professionals must engage patients or their proxies in discussion in which the health professionals explain the clinical situation in detail, and they must also assure themselves that those involved in these discussions fully understand what has been explained. Discussions with patients and their proxies require health professionals and Health care Ethics Committees to discuss the importance of protecting patients' privacy and the confidentiality required with respect to their medical records. This is yet another important bioethical topic for all concerned parties: patients, their families, the attending health professionals, and the members of Health care Ethics Committees.

Owing to the extensive media attention to end-of-life issues, it is no longer prudent or even possible to avoid other bioethical topics, e.g. discussions of 'heart death' and 'brain death', the latter a relatively new phenomenon, brought about by the advent of organ transplantation and the discovery of immunosuppressive drugs to inhibit organ rejection in recipients.

A combination of all the issues noted above have led to widespread interest in and discussions of a plethora of publications directed to 'advance directives'. To assist families, health professionals and the members of Health care Ethics Committees, many have urged the public to prepare written documents – that have legal authority – that would serve to inform health professionals, health care institutions, and Health care Ethics Committees of people's wishes prior to becoming incapacitated patients – when they are no longer able to articulate their preferences and wishes, which may well involve decisions to forgo medical treatment.

### **3.2 An illustrative example of importance to health professionals who treat patients**

**Imminently dying patients: Should health care institutions adopt a policy of prescribing palliative sedation to avoid euthanasia and physician-assisted dying?**

Palliative sedation has unfortunately acquired other names – 'total sedation', 'terminal sedation', even 'slow euthanasia'. It is a procedure aimed at producing a sleep state, a state of total or decreased awareness, a state difficult to discern from unconsciousness, the total absence of self – and this, it turns out, is ethically problematic.

'Terminal sedation' is ambiguous. Does it mean (1) pharmacologically intervening with the intent of providing a terminally ill patient with comfort care, assuaging the patient's intractable pain and refractory suffering, intervening for a person whose prognosis is to live only for a matter of days or at

most a few weeks; or (2) intervening for the purpose of, or causing, the termination of the patient's life – active euthanasia? Clearly not (2), unless the agent, e.g. a physician, is prepared to be charged with intending to kill the patient, and succeeding, i.e. carrying out a criminal act, which would in all likelihood be the case in most jurisdictions.

Whatever the aim of those who advocate palliative sedation, they cannot have as their target euthanasia, since their goal is precisely to avoid any charge that the procedure and its outcomes come to nothing more than euthanasia, however linguistically disguised. And since the procedure of palliative sedation is not initiated by the patient him – or herself, it certainly is not a case of physician-assisted suicide, nor physician-assisted dying – a distinction of importance, but usually overlooked – since this necessarily requires that the patient self – administers the lethal concoction, not the physician, or anyone else.

'Slow euthanasia' is not only a misnomer but begs a key question: whether palliative sedation is euthanasia in any sense, or even physician-assisted dying – no matter how long it takes for the patient *in extremis* to expire following sedation. And here there is no need to raise the question of whether terminal sedation is easily abused by parties closest to the patient (i.e. is it 'treatment' given to a patient for his or her family), or even whether it is easily reversible, though it is appropriate to ask whether health professionals can sedate a patient by titrating the sedatives to produce a patient's complete unresponsiveness until death ensues.

And here we return to the critical bioethical question: Is palliative sedation euthanasia? Some argue that as long as the physician does not intend, when administering palliative sedation, to hasten his or her patient's death, although death is foreseen as a direct consequence of administering the sedatives, the physician is not euthanizing the patient. But is the terminally sedated, pharmacologically unconscious, brain-in-coma, mindless patient any better off than dead – existentially dead from the patient's 'perspective'? If the answer is 'no', then the outcome of palliative sedation is no more and no less morally wrong than the outcome of euthanizing a patient or providing him or her with assistance in dying. Put another way, for the same reasons that one ought not to participate in euthanasia or physician-assisted dying, one ought not to promote or provide palliative sedation. This suggests one salient bioethical dilemma.

## A Bioethical Dilemma:

**Premise 1-A** If physicians elect palliative sedation as treatment for their distressed terminally ill patients based on their patients' values, expressed wishes and informed consent – prescribe sedative pharmacology to induce deep sleep and unconsciousness – then although they will relieve or eliminate their patients' distress, severe refractory symptoms like intractable pain, respiratory distress, and physical suffering – they will also induce 'existential euthanasia' – wherein the patient is no better off than dead; and

**Premise 1-B** If physicians opt to continue to treat their patients' symptoms and to identify potentially reversible, physical causes of their terminal patients' illnesses (i.e. to reject palliative sedation), then their patients may well undergo prolonged distress, unrelieved, intractable pain and physical suffering (although physicians would be unjustly accused of euthanizing their patients).

**Premise 2** Either physicians elect palliative sedation as treatment for their distressed terminal patients or they reject it and opt for traditional treatments in the hope of reversing the course of their patients' illnesses.

**Conclusion** Either physicians end the 'existential' lives of their terminal patients, or they permit them to experience prolonged distress, as well as unrelieved, intractable pain and physical suffering.

The traditional medical ethic articulating that the doctor has a duty to preserve and prolong human life wherever and whenever he or she can and must fight against death under all circumstances with whatever is available in the medical armamentarium, has dominated medical practice for centuries. This medical ethics admits of no exceptions, and virtually compels health practitioners who attend to patients *in extremis* to question its practicality.

Health care Ethics Committee members, once they attend their first meeting, are immediately made aware that among the primary purposes of these committees – (a) individual patient's case review and analyses; and (b) continuing self-education – will be the formation of their health care institution's ethical guidelines and policies. Among the policies that health care institutions adopt, at least one will concern the use or rejection of palliative sedation for patients *in extremis*.

During the committee's deliberations, the following questions may well emerge: What is palliative sedation, and how does it differ from euthanasia and physician-assisted dying or suicide? What arguments have been put forth to justify the procedure? To reject the procedure? If a palliative-sedation policy is adopted, who does what and under what conditions or criteria? How to guard against abuse? How will patients, their families and the local community regard the health care institution and its medical and nursing staffs, if they participate in palliative sedation at the end of life?

Health care Ethics Committee members should take the time required to address these and other questions before they participate in policy development that may be adopted and promulgated by the health care institution.

#### 4. RESEARCH ETHICS COMMITTEES – DUAL MISSION

Research Ethics Committees in an increasing number of Member States have, during the past decade, experienced a rapid rise in the number of clinical protocols requiring their review. Moreover, there is growing consensus that scientific and bioethical aspects of clinical trials, though separable in thought, are not separable in fact: scientific methods and objectives must be addressed in relation to bioethical considerations.

The failure to recognize this symbiotic relationship has served to confuse many of those charged with the review and eventual approval of research protocols, not only prior to initiating but also after terminating these trials. Adding a legal level of complexity, every Member State that allows research with human participants has its own set of rules and regulations to govern the enterprise. The failure to recognize this intertwining is becoming more appreciated as evidenced by the recent concern being paid to the post-marketing research phase, when pharmaceuticals, devices and vaccines are actually being sold to the public.

In addition to the formidable task of reviewing the ethico-scientific-regulatory features of research protocols, a growing number of Research Ethics Committees have also accepted a second role: to participate in investigations of alleged research misconduct, or what may turn out to be misbehaviour (the relation being that between ethics and psychology, respectively). When allegations of researchers' misconduct are received, the traditional approach has been to appoint special panels or committees and authorize them to conduct investigations and to report their findings – perhaps even proffer recommendations.

#### **4.1. Protecting human research participants while facilitating research with risks**

##### **4.1.1. Substantial bioethical issues of importance to investigators and participants in biological, biomedical, behavioural and epidemiological research trials.**

A perusal of bioethics literature and extensive media coverage of bioethical issues in a large number of Member States reveals that scientists-clinician researchers are principally concerned with bioethical issues and dilemmas that emerge in the course of designing studies and experiments that involve the participation of human beings, once an adequate number of animal studies have been conducted.

Since the mid-1960s, a consensus has formed among clinical investigators: the members of Research Ethics Committees in a large number of Member States – when viewed from today's perspective – have selected a set of curriculum topics to assist them in the task of evaluating the scientific, bioethical and regulatory design of clinical research protocols involving human participants.

Members of Research Ethics Committees are now encouraged to study the history of protection systems – in their State – for persons who consent to participate in clinical research trials. This involves discussing ways to distinguish among the scientific, bioethical and regulatory design of clinical research protocols. The members should, in addition, consider the various means and techniques for equitably soliciting and recruiting patients, vulnerable persons as well as healthy persons to participate in these clinical trials.

Principal investigators and other researchers should become sensitive to and appreciate the myriad cultural and value differences among Member States that have a bearing on the behaviour of researchers who conduct pharmaceutical, vaccine, surgical and device trials.

Researchers who serve as members of these Committees should examine the various ways to protect clinical research participants' privacy (and confidentiality of information acquired prior to, during and following research trials). Of greatest importance, is the need for the members to review the risks of physical, psychological, dignitary and financial harms to those who participate in clinical trials, and to focus on the possible benefits to future persons – not only present participants.

The so-called gold standard of sound clinical research is the randomized clinical trial. Committee members should consider alternative research methods other than the randomized clinical trial for acquiring generalizable knowledge; all methods, however, require the informed consent of research participants, unless such consent is waived or deferred by an appropriate authority, as may occur in some emergency research protocols. It is important for members of Research Ethics Committees to consider various ways to protect participants who may become involved in research trials conducted in

an emergency context. Some Member States permit, under certain circumstances, principal investigators not to acquire participants' informed consent if it is unfeasible to acquire consent prior to the time of the actual research intervention.

Finally, all researchers should attend to any potential conflicts of interests beyond acceptable interests of income and reputation proportional to their professional research activities, e.g. excessive honoraria, royalties, inordinate career advancement and reputation.

#### **4.1.2 The dual roles of personal physician and principal investigator: when, if ever, should these roles be combined?**

How are Research Ethics Committees and data-safety monitoring boards to protect participants against therapeutic misconception in clinical research trials? Therapeutic misconception is the frequently held false belief on the part of patients who consent to participate in clinical trials that they will continue to receive the same, if not a superior standard of individualized care and treatment from their physicians as they received prior to participating in the study. Therapeutic misconception is especially likely to arise when the roles of personal physician and principal investigator are combined. For patients often assume that the personal physician role will dominate and that they can expect direct benefits from their participation in a research project. If patient-participants learn that this will in fact not be the case, they may feel betrayed and abused.

This may change their future relationships with physicians as well as discourage them from consenting to participate in research trials. Furthermore, a trial participant does not tend to distinguish the general results of the study in which he or she participated from his or her personal, independent result. And providing a general summary simply does not provide personalized information. Moreover, this information varies depending on the trial-arm to which a participant was assigned. Most researchers appreciate the fact that they are ethically accountable to the participants, who have a right to know the results of the trial. But researchers do not always choose the best method of conveying this information to the participants. At the same time, patients now demand that their physicians keep up to date in their respective fields of specialization, and that their participation as patients in research may be among the best means to this end.

### **A Bioethical Dilemma**

**Premise 1-A** If the roles of personal clinician and principal investigator are merged, then patients who consent to be research participants will be more susceptible to therapeutic misconception (principal investigators will be obliged to reassure their patient-participants that as investigators they do not have a conflict of interests – a tendency to seek scientific knowledge at the price of their patients' welfare); and

**Premise 1-B** If the roles of clinician and principal investigator are kept separate, which is the prevailing model, then physicians who wish to exercise their intellectual curiosity and investigative faculties – especially with regard to alternatives or improved methods of care for their patients – will be discouraged or constrained from pursuing clinical research.

**Premise 2** Either the roles of clinician and principal investigator are kept separate or they are merged.

**Conclusion** Either research participants will be more susceptible to therapeutic misconception (which seriously affects the informed consent process and informed decision-making) or physicians will be constrained from pursuing clinical research whose aim is to explore better treatment alternatives (which will seriously impede the improvement of patient care).

In developing States – unlike developed States – this dilemma may be less salient because there may be too few health care providers available to separate the roles of personal physician and clinical researcher; and these few health care providers may be the only observers in a position to report disease phenomena that are unfamiliar to the mainstream of the profession. An across-the-board ban on merging the roles of clinician and researcher would then be especially harmful to these Member States. A ban might also be harmful to developed States, for it would necessarily require review by persons at a higher administrative and academic level, and this would impose serious inefficiencies and delays. It should be pointed out, since it is often overlooked, that principal investigators, too, are usually deeply committed to their ongoing research and tend to believe, however falsely, that they are on the verge of a new discovery – a safe and efficacious pharmaceutical, vaccine, or surgical technique – before sound and adequate evidence has been acquired. That is, they are also amenable to therapeutic misconception. If they honestly introspect, they will appreciate the fact that they too, not infrequently, tend to falsely believe in the benefit of their work to patient participants – not only future patients. Finally, a serious consequence of sharply separating the roles – clinician and investigator – may be to reduce the clinical provider to making only anecdotal reports of his or her patients' treatment and outcomes, rather than engaging in the scientific rigours of a prospective control trial which he or she would be prohibited from conducting. It is also possible that other physicians may be influenced by these anecdotal reports to prescribe on less than scientific evidence, or that researchers may divert time and effort to investigate what are nothing more than uncontrolled observations. If it appears unfeasible to separate the roles of personal clinician and principal investigator, then Research Ethics Committees need to consider and address ways of reducing the likelihood of therapeutic misconception and confusion about roles in the absence of that separation.

#### **4.2. Sustaining research integrity**

##### **4.2.1. Compromised integrity in research and its bearing on public trust and confidence in scientist-clinicians**

Public attitudes towards medical science and biotechnology have always been driven by ambiguity. People are fascinated with the products of science and technology, and they marvel at the discovery of DNA and the development of safer and simplified surgical techniques. They take delight in imagining what the future may hold – the conquest of disease, perhaps, and a significant lengthening of the average life-expectancy, if not longevity. The scientists and technologists responsible for these advances are honoured for their vision, skill and humanitarian commitment. Yet the public also fears that these scientists and technologists, may be driven by hubris or dominated by greed, that they may adopt an

ends-justify-the-means stance that may invite abuse, or that their wondrous works will be used by unscrupulous others for their own malign purposes.

These public attitudes have led to a growing concern among scientists, technologists and clinical researchers concerning the incremental loss of public confidence in them, as well as a mistrust in science, biotechnology and its applications. Whether this reflects the age-old fear that science and technology are tainted by overbearing pride or more recent concerns that they have been corrupted by the profit motive, researchers must now confront widespread suspicion and distrust. Greatly exacerbating the problem are highly publicized tales of researcher-clinicians' misconduct now spread by the media as though virulent plagues, notwithstanding the fact that there is among scientists only a consensus that no consensus can be achieved regarding a definition of 'misconduct'. The consequences are difficult to predict with precision, but one can be confident that they will undermine the authority of clinician-researchers and thus discourage able persons from entering the profession, discourage governments and businesses from making risky investments, deter patients from participating in trials, and dissuade patients from agreeing to undergo invasive procedures. The need for scientific organizations and health professions aggressively to retake the moral highground could hardly be greater.

The growing science-industry research complex also heightens the tendency of the public to remain sceptical about science, clinical research, and biotechnology, all intertwined with the background, interests and values of scientists and clinicians themselves. Finally, only quite recently has professional attention refocused on the importance of maintaining high moral standards among scientists, clinicians and technicians, standards that may, in time, reflect young scientists' personal integrity and their commitment to socially responsible research, and the commitment to avoid at all costs the extreme form of misconduct – criminal fraud.

Although no exhaustive definition of scientific 'misconduct' has been achieved, it is instructive to review the consensus statement (reproduced below) of The Royal College of Physicians of Edinburgh (U.K. - October, 1999) concerning the promotion of good research.

#### **PROMOTING RESPONSIBLE RESEARCH**

- 1.** By affirming a culture through example in which honesty and integrity are expected of every individual and misconduct is not tolerated.
- 2.** Through education, training and vigilance from the outset, starting with undergraduate entry and continuing through lifelong learning.
- 3.** By ensuring formal training of all supervisors of research.
- 4.** By establishing effective and efficient mechanisms for mentoring, auditing and ethics review, appropriate to the design of the study.
- 5.** By provision of expert advice, guidance and training for [research] ethics committees.
- 6.** By respecting consent and confidentiality.

7. By having a framework for and promulgating written guidance on good research practice including publication policy and dissemination of results.
8. By designing procedures to ensure that funds are only allocated within a framework for good research practice and when local systems for managing allegations of research misconduct are shown to be established and effective.
9. By investigating all allegations of research misconduct firmly, fairly and expeditiously.
10. By developing effective and impartial local systems for employers...to manage allegations of research misconduct, including reference to disciplinary procedures or referral for criminal investigation.
11. By providing access to appropriate support for whistle-blowers and researchers.

#### 4.2.2. Scientific misconduct and the breach of public trust and confidence in clinical research

##### Case A: Human stem cell research

On 12 February 2004, the journal *Science* received a research paper on stem cells from Woo-suk Hwang, D.V.M., Ph.D. – a member of the Department of Theriogenology and Biotechnology, College of Veterinary Medicine, Seoul National University, the Republic of Korea – and others [see (a) below]. The editors initiated the journal's standard procedures, including anonymous peer review, but recognizing the significance of the paper, radically speeded up the process, marking it 'express'. The paper was accepted and published one month later.

Following the publication of another research paper by Dr Hwang, et al. in the British journal *Nature* in August 2005 [see (b), below], which reported the first successful cloning of two Afghan hounds, Dr Hwang and 24 other authors published another paper in *Science* on 17 June 2005 [see (c) below]. Once again, the editors had marked it 'express' when it was received on 19 May 2005, a month earlier.

#### CASE REFERENCES

1. Hwang, W.S., Ryu, Y. J., Park, J. H., et al. 'Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst', *Science*, 303 (5664): 1669 – 1674, 12 March 2004.
2. Lee, B. C., et al. – G. P. Schatten and W.S. Hwang – 'Dogs Cloned from Adult Somatic Cells', *Nature*, 436 (7051): 641, 4 August 2005. [Snuppy – one of two Afgan hounds – cloned from ear cells of a male, Tai. This claim was upheld by Seoul National University's Investigation Committee. (<http://www.snu.ac.kr/>)]
3. Hwang, W.S., Roh, S. I., Lee, B. C., et al. 'Patient-Specific Embryonic Stem Cells Derived from Human SCNT [Somatic Cell Nuclear Transfer] Blastocysts', *Science*, 308 (5729): 1777 – 1783, 17 June 2005. [Gerald P. Schatten, Ph.D. – Department of Obstetrics, Gynecology and Reproductive Science and Director, Pittsburgh Development Center, University of Pittsburgh School of Medicine, Pennsylvania, U.S.A – was co-corresponding and senior author, a prestigious position in the Republic of Korea.]

The first stem cell paper in *Science* described an oocyte retrieval method, which produced a cloned human embryo (blastocyst), reporting that DNA from a human embryonic stem cell line was identical to that of the donor. This biomedical cloning procedure is known as Somatic Cell Nuclear Transfer, or simply nuclear transfer (see the UNESCO publication *Human Cloning*, 2004). The stem cell line was allegedly derived from the embryo (blastocyst) produced by transferring the nucleus of a somatic (non-reproductive) cell, which contained a woman's 'genetic blueprint', into a nucleus-free oocyte from the same donor.

These procedures should serve to remind us of the technique's human significance and the fact that the outcome, if it had been realized, would without doubt have been a living cloned human embryo, the functional equivalent of a woman's fertilized egg.

Furthermore, Dr Hwang and his colleagues claimed to have developed 'versatile' embryonic stem cells potentially capable of becoming any human cell type. This would have constituted the first important step towards healing patients with their own genetically regenerated tissue literally their own DNA.

This opened up the prospect of converting a patient's adult cell into an embryonic cell, which would then be converted into new adult cells, where they would replace or repair damaged tissue as the result of some ailment (diabetes) or injury (severed spinal cord). The benefits were potentially incalculable.

Sadly, this complex, subtle, tedious and time-consuming process undertaken by the research team led to numerous false claims, e.g. that eleven patient-specific stem cell lines were derived and collected from cloned human embryos. Indeed, it was later determined that not even one was cloned.

The publications in *Science* and the immense media attention they engendered transformed Dr Hwang into a scientific celebrity and a national hero, so renowned that the Republic of Korea printed a postage stamp in his honour. As quick as had been his rise, however, was his fall. The media immediately dubbed this an 'ethics debacle' since it involved serious ethical lapses on the part of Dr Hwang and some members of his extended research team who, it was determined, lied to scientific journals (falsely claiming that all the oocytes were donated by volunteers), fabricated evidence (falsely claiming that nine of eleven patient-specific stem cell lines were cloned when in fact none was cloned), falsified and concealed scientific data, ignored contradictory facts and intended to deceive.

The research raised interesting questions. Inasmuch as the egg donors were at risk for a variety of serious harms (ovariocentesis, renal failure, blood clots, infertility and death), were they due any compensation? They received no direct medical benefit from the procedure and apparently many were not paid. It should not go unnoticed that by present standards these women were research participants – a special subset – 'donor participants'. As research donor participants the women had no ownership rights in the technology and would not be able to share in any financial or other benefits. If any benefits were forthcoming, they would accrue to sick patients, the hope being that therapeutic or (more modestly and with less hyperbole), biomedical cloning would be the first important step towards healing patients with their own genetically identical regenerated tissue, their own DNA.

There were other forms of scientific misconduct, e.g. the failure to obtain duly informed consent from all the women oocyte donors, some of whom, it was alleged, were 'junior researchers' who were

under social pressure to please their superiors. Inasmuch as the donors had participated in the research in a subordinate status, had they freely consented to the procedure? Pressure, even if unspoken or unacknowledged, may easily have compelled their agreement. The issue of whether compensating these women for their 'donated' oocytes was ethically warranted is not only a legal but also a continuing bioethical controversy, which aroused debate, and involved at least one salient bioethical dilemma.

## A Bioethical Dilemma

**Premise 1-A** If stem cell researchers are permitted to pay women for the risks involved in retrieving their oocytes (or even their time – approximately 56 total hours in a medical setting – inconvenience, discomfort and unknown risk of harm from anaesthesia and bleeding, e.g. the use of hollow needle sticks under anaesthesia to retrieve their oocytes), when they conduct therapeutic or biomedical, as distinguished from reproductive, cloning research – then human life will be commodified; and

**Premise 1-B** If stem cell researchers are prohibited from paying women for their oocytes and the risks involved in retrieving their oocytes, when they conduct biomedical cloning, then the voluntary donation of oocytes will be sharply curtailed and the potential benefit and human stem cell research seriously inhibited.

**Premise 2** Either it is permissible to pay women for their oocytes and the likely collateral consequences, or it is impermissible.

### Conclusion

Either human life will be commodified, or research will be seriously curtailed, leading to avoidable morbidity and mortality.

Members of Research Ethics Committees committed to pursuing their bioethics education might reflect on this dilemma and the assumptions it entails before setting out to resolve it. Premise 1-A, for example, presumes that commodification of the body, in this case payment for and the sale of oocytes, is unethical. Yet some societies endorse and permit the sale of male gametes, spermatozoa. The Republic of Korea, for example, only recently enacted legislation to prohibit payment for gametes, although everywhere it is taken for granted that compensating researchers is not ethically problematical.

Given this bioethical dilemma, and others, it should be noted that the Republic of Korea responded to this imbroglio by imposing even stricter human oocyte-donation regulations on researchers than apply in some other Member States. This was accomplished through a law regulating highly sensitive stem cell research and establishing an oversight committee, with seven of its twenty-one seats reserved for Government ministers. At present, no laboratory in the Republic of Korea is permitted to conduct stem cell research, and Dr Hwang's licence, giving him permission to conduct stem cell research, has been revoked by the State's Health Ministry.

Notwithstanding these recent actions and new regulations, the scientific research enterprise has for almost two centuries, relied principally on trust and the doctrine of lesser harms, a risk-benefit doctrine accepted by the broad scientific community. This doctrine holds that an intervention is ethically

justified if and only if the risk of harms it involves are less than the risks of disease that the intervention is designed to prevent or treat.

Embarrassed and threatened by new breaches of trust, scientific and medical authorities will surely greet reports of breakthroughs with extreme caution in the future. The editors of scientific and medical journals and their peer reviewers will do the same, especially since it has recently come to light that various forms of manipulation of manuscripts and photographs are not always easily detectable and no longer difficult to introduce into print.

It is fortunate that the Republic of Korea has a well organized Bioethics Association. Chairpersons of Research Ethics Committees should consider inviting members of this Association – as well as renowned stem cell researchers, health lawyers, and bioethicists from the Republic of Korea and other nations – to their meetings. This could serve to enhance the education of the Committee's members with respect to both the protection of research participants and ways to avoid investigators' misconduct. Whether this Association establishes a panel or special committee that includes scientist-researchers from other Member States, further to guarantee the committee's objectivity and to assist in ensuring that the nation's biomedical researchers meet strict national and international ethical standards, critics from other nations might best adopt a 'wait and see' strategy. One possibility is to make use of UNESCO's International Bioethics Committee in these cases. The committee as an independent and neutral international body of experts might be used to provide expert advice and assessment of problematic cases in order to apply the normative instruments adopted by the Organization's Member States, and give advice for policies.

The 25 authors of the 2005 paper *in Science* included Gerald P. Schatten, Ph.D., a faculty member at the University of Pittsburgh School of Medicine; he was co-corresponding and senior author of the research paper. Following the publication of the 2005 paper, the University of Pittsburgh Research Integrity Panel was charged with investigating Dr Schatten's involvement in this research protocol. Although the panel found that there was no evidence that Dr Schatten committed scientific misconduct – its report states that he 'likely did not intentionally falsify or fabricate experimental data' – he was found guilty of 'research misbehaviour'. The panel members identified a number of shortcomings in Dr Schatten's fulfilment of his responsibilities as co-author of this article, and their findings were accepted by the University's Administration. The shortcomings include the failure to:

(1) 'exercise a sufficiently critical perspective as a scientist', (2) 'assume responsibility' for including false statements in the manuscript, (3) assume responsibility 'for the manuscript as a whole', (4) obtain 'approval of the manuscript by all co-authors', and (5) obtain approval of all co-authors regarding 'the veracity of the data reported'. To his credit, Dr Schatten wrote to the editors of *Science* on 12 December 2005 'to initiate retraction of the paper'. It was retracted on 12 January 2006.

As time passes, and Research Ethics Committees continue to convene and carry out their functions, their members may discover that they need to intensify their formal education. This applies to the Research Ethics Committees' dual functions. That is, it will not be sufficient for members to examine only one case scenario involving scientific misconduct. Regrettably, additional cases and scenarios are being reported more frequently; on occasion the timing is startling.

### Case B: Treating oral cancer

At about the same time as the Republic of Korea stem cell scandal, other fraud charges arose halfway around the world. Dr Jon Sudbø and others, who practiced at Radiumhospitalet in Oslo, Norway, published at least three blatantly fraudulent research papers in prestigious journals: the first in *The New England Journal of Medicine* [see (a) below], where Dr Sudbø manipulated a photograph he had already published in an earlier issue of the same journal (26 April 2001; 344: 1270 – 1278); a second in *Journal of Clinical Oncology* [see (b) below], where he later confessed to fabricating data in this oral cancer study; and the third in *The Lancet* [see (c) below], where, among other things, he ‘invented’ a large number of patients among the 908 study participants, 250 of whom, so it was noted, shared the same birth date. As one editor remarked – following a thorough review of the publication – it is ‘just complete fabrication’.

#### CASE REFERENCES

1. Sudbø, J., et al., ‘The Influence of Resection and Aneuploidy on Mortality in Oral Leukoplakia’, *The New England Journal of Medicine*, 350(14): 1405 – 1413, 1 April 2004.
2. Sudbø, J., et al., ‘Risk Markers of Oral Cancer in Clinically Normal Mucosa as an Aid in Smoking Cessation Counseling’, *Journal of Clinical Oncology*, 23 (9): 1927 – 1933, 20 March 2005.
3. Sudbø, J., et al., ‘Non-Steroidal Anti-Inflammatory Drugs and the Risk of Oral Cancer: A Nested Case-Control Study’, *The Lancet*, 366 (9494): 1359 – 1366, 15 – 21 October 2005.

Soon thereafter, Dr Sudbø’s research was cited widely, including the American Cancer Society’s website. Further, a number of journal editors began to review Dr Sudbø’s prior publications, especially where he was listed as lead author, to determine if any other publications warranted allegations of scientific misconduct. An independent review commission, headed by a researcher from the Karolinska Institutet, has been charged with investigating the case, which will involve a review of virtually all of Dr Sudbø’s scientific publications.

These egregious acts of scientific misconduct led the Norwegian Government to consider formulating a statute under which researchers who are found guilty of scientific misconduct may be jailed. Such serious punishment had in all likelihood been proposed in part because in this case of scientific misconduct, unlike Dr Hwang’s, Dr Sudbø’s published papers actually endangered patients with regard to increased risk of harmful cardiovascular complications as a direct result of promoting, on the basis of his ‘scientific evidence’, the prescriptive use of non-steroidal anti-inflammatory drugs in place of standard surgery, to reduce the risk of oral cancer. Researchers, influenced by Dr Sudbø’s published ‘findings’, moreover, initiated new studies concerning the effect of anti-inflammatory drugs on oral cancer, and inadvertently added to the harms, and were also victimized.

Ironically, in the 10 July 2003 issue of *The New England Journal of Medicine* (10 [3249]: 190), the editors had published a letter from Dr Sudbø (in his reply to ‘The Protection of Human Subjects’)

declaring, 'The results of rigorously conducted clinical trials make up the foundation for what we like to term "evidence-based medicine" (...) Consequently, physicians may decide not to offer a treatment because the evidence does not support its use in clinical circumstances such as advanced age. This matter, too, merits ethical consideration'.

Various media report that according to Dr Sudbø's attorney, his client's motive was 'not about money'. Perhaps it was about vaulting ambition or the need for prestige, international recognition, priority for a discovery, pressure to publish, to garner a promotion, to succeed in the competition for future research grant awards or potentially lucrative patents, or some other need for preferment. In any case, for reputable researchers there is no worse feeling than to learn that as co-authors they have put their names to a fraudulent paper. As one researcher put it: 'We are shocked. This is the worst thing that could happen in a research institution like ours'.

It should be noted, however, that in spite of the increasing evidence of researchers' misconduct in the context of publication, scientific and biomedical knowledge continues to advance efficiently and new biotechnologies continue to emerge without interruption. Yet an important question persists: how are Research Ethics Committees and university-appointed review panels in both public and private research institutions – charged with investigating allegations of research-scientists' misconduct – properly to protect the participants, as well as other researchers, from fraudulent acts by some scientist-clinicians?

#### **4.2.3. How should fabrication, falsification and fraud in science be forestalled?**

With respect to the short-term, at least, continuous regulation and monitoring of scientists' and researchers' activities may become the chosen strategy of Member States, though regulation inhibits efficiency, hinders innovation, and is profoundly hostile to the spirit of free scientific inquiry. Yet the self-correction of science operates imperfectly. It is rarely feasible to replicate large studies, for example (though even here, reanalysis of primary data may be very instructive). Further monitoring and oversight of research, of course, may to some degree interfere with the interactions between researchers and the industry sponsors who continue to support the multinational research enterprise. This, in turn, may well induce the scientific research community to take steps to protect itself from excessive, external regulatory oversight. Yet, suspicions of cover-ups will persist. Institutions' interests in safeguarding their reputation and their revenue flows will often trump ethical obligations.

Not only government agencies but the editors of scientific and medical journals are also establishing procedures and policies to deal with breaches of publication ethics. With over 54,000 scientific and medical journals, they are too numerous to be adequately monitored. Nor are their publishers ready to undertake wholesale investigations. Although a small number of journals are truly influential, they can only go so far in their inquiries before seeking the assistance of government agencies and professional associations charged with overseeing scientific and medical research.

Though it is impossible to prevent all scientific misconduct and also to ensure that dishonest people do not become members of research review committees, some preventive action can be taken. One approach involves a number of formal and informal research-oversight stratagems. They are not

a panacea since the stratagems, if followed seriously, will quite likely serve to decelerate the research enterprise which some, but not all, will applaud.

## A. Formal Stratagems

1. Require researchers to adhere to government-mandated regulations that include the requirement that all research protocols be scientifically sound. This will require the collaboration of panels of technically competent scientists to review these protocols and apply evaluative standards shared by members of a broad, not merely local, scientific community.

2. Establish statutory advisory panels authorized to regulate the case-by-case review of controversial drug studies, and have the panels create a mechanism for evaluating (a) the safety of ongoing human research protocols and (b) any corporate/industry-university entrepreneurial arrangements that could compromise the safety of research participants, bias research conduct and published results, or, in time, compromise post-marketing oversight of pharmaceuticals.

3. Ensure that advisory and oversight committees have at least one member with expertise in pharmacology and another in toxicology.

4. Ensure that members of oversight committees are provided with a flow of adequate information, particularly with reference to adverse effects, in order to enhance the likelihood that their assessments will be effective, i.e. prevent foreseeable injury to research participants.

## B. Informal Stratagems

1. Repeatedly inform the public of the danger of researchers' hyperbole with respect to any new biotechnology.

2. Officially appoint highly competent and experienced laboratory scientists on drug oversight committees, since they tend to be more sceptical of claims about short-term therapeutic benefits for patients.

3. Officially appoint highly competent and experienced clinical-research scientists on drug, device and vaccine review committees. They will in all likelihood appreciate the history of the internal norms of science, understand the burden of risk of harms to research participants, and be comfortable utilizing their professional networks to conduct their reviews.

4. Establish a favourable culture of collaboration (with proper checks and balances), for promoting scientific activity, whose long-term consequences benefit the sick and dying, and thereby reduce the likelihood of future ethics debacles.

## Part IV

### EVALUATING THE EDUCATIONAL ACCOMPLISHMENTS OF BIOETHICS COMMITTEE MEMBERS

Any programme undertaken to improve the knowledge and enhance the competence of members of Bioethics Committees must eventually confront the question of how successful it truly is. Periodic evaluation is one answer, and it must be taken seriously.

Evaluation may be either formal or informal. Formal evaluations may involve inviting an external organization to conduct a study. Drawing on interviews with present and past committee members and those who have dealt with them, plus examination of relevant documents and records, an organization could effectively audit the performance of a Bioethics Committee. Measurement may not be easy, however. Experienced, externally-based bioethicists should be able to reach general conclusions and offer helpful corrective criticism.

This approach would be expensive, however, and might strike committee members as threatening.

Accordingly, most institutions choose to rely on self-evaluation. Formal self-evaluation might have the committee interviewing its own members to elicit their views on its practices, procedures and results. The problem with this approach is that it cannot avoid the charge of conflict of interest: the committee would be grading itself. Another problem is that if the self-evaluation is truly rigorous, it will discourage many persons from joining the committee, and some of these might have been valued members who would reject being tested.

The goal, then, would be to create a committee culture that insists on high performance. Peer pressure can be a powerful force for excellence, and the very activity of evaluation may be a valuable educational experience as members learn more about themselves as well as the substantive subject matter of bioethics. Although a Bioethics Committee's education is usually quite informal – each member following suggestions from the chairperson or other members – formal evaluation techniques may prove most helpful to the chairperson and the committee's bioethicists as well as to the members.

#### BIOETHICS COMMITTEE MEMBERS' EVALUATION OF THEIR SELF-EDUCATION

##### INFORMAL



1. Discuss reading materials
2. Members' discussions
3. Brief presentations / papers

##### FORMAL



1. External examiners
2. Written tests
3. Oral quizzes

Each member should have had time to read about bioethical issues germane to the committee's mandate and goals. The result of each member's formal evaluation need not be made available to the full membership, but the chairperson should see the results to help him or her decide whether specific members should be reappointed.

Most committees' activities, including self-education, are invisible to outsiders, since outsiders usually lack knowledge of bioethics or the committees' activities. On the other hand, there are bioethicists who have expertise in teaching a wide variety of students, including scientists and health professionals. These experts are usually ready, willing and able to serve as educators, though one must be aware that not all those claiming to be experts are actually expert.

Bioethics Committees, however, can call upon bioethicists known to have extensive experience in the field, who may have worked in health care settings or served on medical, nursing or pharmacy faculties. Bioethicists should be in a position to assist in the evaluation of the bioethical knowledge of committee members. They should identify the strengths and weaknesses of the members' ongoing self-education, and offer concrete suggestions that in time lead to improvement of the members' contributions to the meetings.

If a committee fails to address evaluation of its self-education programme, the danger is that it will become less effective, lose credibility and forfeit long-term viability. Moreover, specially qualified persons who might have been willing to serve on the bioethics committee may be discouraged from doing so.

A second question posed by evaluation of a committee's self-education is how success is to be defined. The simplest answer is to view success as a function of the goals of the committee.

But this may not be easy to measure. Is it possible to evaluate to what extent Health care Ethics Committees, whose members become further educated in bioethics, improve patient-centred care? Do Research Ethics Committees, whose members are dedicated to the acquisition of new knowledge, and are involved in a programme of self-education in bioethics, actually protect those who participate in research trials? And how can we be sure that the goals are appropriate? Easily achieved goals may indicate great success but not much progress.

Another approach would be to define success in terms of satisfaction: how satisfied are the committee's own members with the bioethical knowledge they have acquired? Their views are important. Yet one sign of an incompetent member might be that he or she is satisfied with the little he or she knows. As important as it is, then, the evaluation of each committee's self-education programme and the advancement of knowledge of its members is notoriously difficult to carry out. Still, it is essential that Bioethics Committees understand that evaluation of their progressive self-education in bioethics is not a time-wasting intrusion or a threat to their good works, but a continuing opportunity to think deeply and carefully about what they do with an eye to helping them do these things better. If committees fail to address the evaluation of their self-education and the bioethics programme they have adopted, they risk undermining their own authority and usefulness.

**WHEN BIOETHICS COMMITTEE MEMBERS FORMALLY AND INFORMALLY  
EVALUATE THEIR SELF-EDUCATION THE MEMBERS SHOULD:**

1. periodically re-evaluate their educational progress
2. record strengths and weaknesses and be willing to continue self-education and attend to any weaknesses
3. be willing to call upon external experts to enhance their self-education

## Part V

### **SUGGESTED TOPICS FOR EDUCATING BIOETHICS COMMITTEES**

UNESCO's Member States not only reflect extensive cultural diversity, but also a multiplicity of values and norms. This is clearly acknowledged in Article 12 of the Declaration: 'The importance of cultural diversity and pluralism should be given due regard'.

Hence, this state of affairs must be addressed when suggesting bioethical topics and reading materials germane to the self-education of the members of Bioethics Committees. For example, topics of interest to Asian or European States may not have priority in African, Latin American, or Arab States, and conversely. To take cultural diversity and ethical pluralism properly into account requires a number of topics and course materials to be set out, providing options to committees when they select topics and prepare to initiate education programmes for their members. The following Appendices provide examples of teaching programmes particularly focused on members of ethics committees.

## Appendix I

### SOUTH AFRICAN RESEARCH ETHICS TRAINING INITIATIVE (SARETI)<sup>2</sup>

#### GENERAL INFORMATION

- SARETI is a comprehensive and multi-disciplinary education programme in health research ethics for Africa. SARETI aims to build African capacity for the ethical review of health research, and to strengthen Africa's institutional training capacity necessary to achieve and sustain this.
- SARETI provides a variety of educational programmes, varying from short workshops and short courses to full Masters programmes.
- The partners in SARETI are the University of KwaZulu-Natal (School of Psychology) the University of Pretoria (School of Medicine), and the Johns Hopkins University (Bioethics Institute, Bloomberg School of Public Health).

The South African Research Ethics Training Initiative is a comprehensive, multi-disciplinary, Africa-based education and training programme in health research ethics. The collaborators in this consortium are the University of KwaZulu-Natal (*School of Psychology, the HIV/AIDS Vaccine Ethics Group*, the University of Pretoria (*School of Medicine, School of Health Systems and Public Health, Centre for Human Rights, Faculty of Law*, and Centre for Professional and Business Ethics), and the Bioethics Institute at the Johns Hopkins University's Bloomberg School of Public Health.

The overall goal of the SARETI training programme is to build African capacity for the ethical review of health research, and to strengthen Africa's institutional training capacity necessary to achieve and sustain this aim. To achieve these goals, SARETI offers a Training and a Support programme. SARETI Training comprises a multi-disciplinary, modular *Masters degree programme* with funding for 14 trainees over the 4 year period of this award; an *advanced, non-degree programme* resulting in a Certificate for self-funded students and a 3-week *training programme for Ethics Review Committee members*. More students are expected to participate using funding outside this award.

#### **The core of the advanced training programme consists of**

1. modular learning at each of the collaborating institutions,
2. practical work with ethics review committees, and
3. the completion of a dissertation / research paper on a topic of relevance to strengthening health research ethics at the trainee's home institution.

#### GOALS AND DELIVERABLES

The overall goal of the SARETI training programme is to build African capacity for the ethical review and implementation of health research, and to strengthen Africa's institutional training capacity to achieve and sustain this aim.

<sup>2</sup> <http://shsph.up.ac.za/sareti/sareti.htm>

## **GOAL 1:**

**To provide advanced, multi-disciplinary education in health research ethics to senior professionals in Africa whose work impacts on health research ethics**

### **Specific Objectives:**

- to offer Masters and Certificate education to senior health professionals and academics enabling them to provide leadership in health research ethics in Africa
- to create a learning environment that provides trainees with substantial theoretical and practical learning in research ethics in bio-medicine, public health, and the social and behavioral sciences
- to provide trainees with a foundation in philosophy, bioethics, human rights, law, research design and research methods
- to provide trainees with a set of critical application areas for health research ethics in developing countries
- to provide trainees with practical learning in terms of institutionalising ethics review of health research and skills in teaching health research ethics to others
- to stimulate trainees to publish their work in health research ethics
- to organise an African Health Research Ethics Symposium every 4th year of this programme (2006 and 2010)

## **GOAL 2:**

**To strengthen institutional capacity to continue health research ethics education, development and research in Africa**

### **Specific Objectives:**

- to create an integrated, multi-disciplinary health research ethics training platform
- to provide further training opportunities to faculty in the two African academic institutions
- to promote the utilisation of SARETI modules by faculty in all disciplines that conduct research in the health field, including economics, environmental sciences, engineering, and business sciences

## **GOAL 3:**

**To increase Ethics Review Committee awareness of ethical issues in health research**

### **Specific Objectives:**

- to offer training modules for members of Ethics Review Committees
- to offer topical 'continuous professional development' workshops

## **GOAL 4:**

**To extend the impact of SARETI programmes by facilitating networking of professionals with health research ethics training and experience in Africa.**

### **Specific Objectives:**

- to fund one of the SARETI Masters trainees to present his/her work at the Global Bioethics Forum or similar conference annually
- to arrange for a meeting every 4th year of this programme that will bring together all SARETI trainees and faculty for the purpose of presenting work in health research ethics, of networking, and of encouraging trainees to continue working in this field – the first such meeting took place in Dakar in October 2006
- to create a link for SARETI trainees to meet with trainees from the Bioethics Institute
- to use SARETI graduates as teachers and field supervisors for future trainees
- to link trainees to the Pan-African Bioethics Initiative (PABIN)
- to facilitate the formation of an African Health Research Ethics interest group within PABIN

## **MODULES (ONE WEEK DURATION)**

### **1. Introduction to Philosophy for Health Researchers**

This module provides insight into historical and current trends and concepts central to philosophy, and will cover a variety of approaches to decision-making in ethics and philosophy. Topics include the mind-body problem; the individual and community; the ethics of experimentation; human mastery over nature, and transcendental versus human powers. It also covers a basic approach to concept development and analysis, principles of logic and structure of logical arguments, hermeneutics and critical thought.

### **2. Evaluating Research Designs**

This module enables students to evaluate the design adequacy of research proposals, so that the ethical aspects of the research can be evaluated. Students will learn to evaluate the following aspects of medical, epidemiological, and social health research designs: elements of sound research design; research design implementation; research capacity and resources.

### **3. Introduction to Bioethics**

This module provides students with the foundations of bioethics in health practice and research. Basic bioethical principles will be covered, as well as alternative bioethical frameworks; identification of bioethical dilemmas and skills for resolving these systematically.

### **4. Institutionalising Ethical Review of Health Research**

This module focuses on implementing institutional ethics review of research. It covers all aspects of Ethics Review Committees: functioning; requirements and existing guidelines; different models; relationships with host institutions; and facilitating and maintaining institutional change. Role plays and participation in actual Ethics Review Committees will enhance the practical nature of this module.

### **5. Public Health, Ethics and Human Rights**

This module enables students to understand ethical and human rights reasoning in health

interventions and research, and provides competence in ethical review of public health research and interventions. The module covers ethical and human rights approaches and applies them to public health. Students deal with threats to ethics or human rights in public health action, and with some specific areas: resource allocation, gender and research, environmental justice, international collaborative research.

#### **6. Introduction to Human Rights for Health Researchers**

This module gives students an awareness of human rights implications of health research, and will provide a basic introduction to human rights, international covenants and other relevant material; it refers specifically to the South African Bill of Rights and to other relevant African documents in law and human rights, and encourages students to apply these to health research.

#### **7. Critical Issues in Informed Consent**

This module focuses on the centrality of informed consent in health research. The historical, philosophical and legal aspects of informed consent are outlined. Controversy surrounding informed consent procedures in vulnerable populations is highlighted, with particular reference to international health research associated with women, children and poverty. Students will develop an awareness of the complexity of these issues and be able to develop appropriate ethical responses.

#### **8. Behaviour and Research**

This module aims to help learners identify the central role of behaviour in health research. Two particular aspects are given attention: the centrality of behavioural issues in ethical health research, as well as ethical issues in behavioural research. These are presented as complementary facets of ethical issues in health research. Case studies are used to examine the relation between behaviour and ethics in research.

#### **9. Professional Ethics in Health Research**

The module covers the interface between professional regulations, professional ethics, and research ethics, which is particularly important in international research and settings with poor regulatory infrastructure. Students will identify issues in health research that require the maintenance of high professional ethical standards and research integrity in the absence of clear regulatory or ethical guidelines.

#### **10. Culture, Morality, and Comparative Ethics**

This module will sensitise students to models of morality and ethics that are common in African settings and which differ from Western ethical approaches. Such approaches are often communal and contextual. Students will cover issues in cultural relativity and absolutism, and become aware of power differentials which impact on ethical health research work in the context of such culturally based moral diversity.

### **11. Ethical Issues in Community Based Research**

This module addresses ethical issues of community entry and participation in health research, particularly in developing countries. Complex ethical issues arise at the interface between researchers and community. Students will identify multiple responsibilities that arise, and identify the shortcomings of traditional professional and research ethics principles in such settings. Students will resolve ethical dilemmas in community participation through critical reflection and interaction.

### **12. Ethical Issues in Women's Health Research**

This module addresses ethical issues of community entry and participation in health research, particularly in developing countries. Complex ethical issues arise at the interface between researchers and community. Students will identify multiple responsibilities that arise, and identify the shortcomings of traditional professional and research ethics principles in such settings. Students will resolve ethical dilemmas in community participation through critical reflection and interaction.

### **13. Ethical Issues in HIV Vaccine Trials**

This module exposes students to the complexities and controversies associated with ethical issues in HIV/AIDS vaccine trials in developing countries, and covers relevant international and local ethical guidelines. Students will apply ethical thinking to particular circumstances in HIV vaccine research

### **14. Religion and Ethics in Health Research**

This module sensitises students to different value systems informed by religion, and the implications of these for health research. It will examine the similarities and differences of some of the world's major and minor religions, and explore the ethical dimensions of such comparisons. Students will be taught to recognise such dimensions in health research contexts and to identify the problematic issue of moral relativism. Africa's major religions, Christianity, Islam and indigenous religions are discussed.

### **15. Ethical Issues in International Collaborative Health Research**

Ethical issues in international health research and concerns about exploitation of vulnerable populations are becoming increasingly prominent. This module identifies risks and concerns, discusses globalisation of health research, and reviews national and international mechanisms to deal with these, particularly in the context of Africa and research in rural areas. Case studies and group discussions will be used.

### **16. Children and Health Research**

The aim of the module is to ensure that the students are sensitized to all issues that relate to children and health care research. The research must be appropriate and of direct benefit to children. The students must be able to objectively review the informed consent process with the parent/guardian as third party consent, as well as the assent of the child if applicable. Special attention will be given to the cognitive development of children and the assent process.

### **17. Practical Ethics Committee (IRB) Participation**

This module will provide students with vital practical experience in attending Research Ethics Committee meetings in a variety of settings. Trainees will be asked to contribute to ethics review of actual research protocols, and trainees will have to integrate and apply the theories and skills acquired in other modules of this course. Assignments encouraging critical reflection will be set.

## Appendix II

### **PAKISTAN BIOETHICS PROGRAMME**

*AGA KHAN UNIVERSITY, Karachi, Pakistan.<sup>1</sup>*

#### **GENERAL INFORMATION**

A broad-based bioethics education programme called the '**Pakistan Bioethics Programme: Gateway to the Islamic World**' is being developed that will offer a comprehensive Masters in Bioethics and several focused Certificate Courses in different areas of bioethics. This programme is aimed at attracting professionals from all over Pakistan, the region and the Islamic world. The syllabus is being designed to attract professionals from a variety of backgrounds including physicians, nurses, hospital administrators, pharmacists, medical educationists, social scientists, philosophers, lawyers, journalists, etc. This programme will be different from the ones being offered in the West as it is being developed taking into account the Islamic, regional as well as Western perspectives.

#### **EDUCATION PROGRAMMES**

The education programmes in bioethics have been designed keeping in mind the socio-cultural context of the region. The objective is to offer bioethics education that is broad based and takes into consideration not only the Western philosophies to which much of today's bioethics owes its origin, but also analyses the Islamic philosophy and its influence on moral discourse and its impact on bioethics in this region in particular and in the Islamic world in general. This strategy sets this programme apart from other bioethics education programmes being offered in the Western world.

A module based educational strategy is being developed to offer education in bioethics. The modules will be running concurrently throughout the year and there will be three entry points into the programmes through the basic module in January, September and May of each year. Two types of programmes will be offered: a comprehensive Masters in Bioethics and four Certificate Courses.

#### **PEDAGOGY**

Each module will be spread over several contact sessions, with each session being of four hours duration. Relevant reading material will be made available to the students well in advance with the expectation that eight hours of reading will be required to prepare for each four hour contact session. An interactive group based learning strategy will be used.

#### **MASTERS IN BIOETHICS**

This programme is aimed at professionals from a variety of fields who have a direct or an indirect role to play in health care and who desire in depth knowledge of bioethics. This can include physicians,

<sup>3</sup> <http://www.aku.edu/bioethics> (accessed 20 October 2006)

nurses, researchers, pharmacists, hospital administrators, health ministry officials and other policy makers, lawyers, medical journalists, social scientists, philosophers and others. It is expected that completion of the Masters in Bioethics will enable these individuals to play leading roles in setting up bioethics educational programmes and bioethics processes like various ethics committees at their institutions.

The coursework for the Masters programme will consist of completion of five modules and submission of a dissertation based on original research in an area of bioethics. This comprehensive programme will be offered on full time or part time basis. As a full time commitment the modules as well as the dissertation can be completed in one year. For individuals desiring a part time commitment, the programme can be completed over three years, the modules taken separately at the convenience of the student followed by submission of the dissertation.

### **CERTIFICATE COURSES**

Four certificate courses will be offered in the following areas:

- Research Ethics
- Clinical Ethics
- Bioethics Education
- Health Equity, Policy and Ethics

These will be offered to individuals desiring to raise capacities in specific areas of bioethics like Ethical Review Committee members, Hospital Ethics Committee members, hospital administrators and government or institutional policy makers seeking instructions in focused areas only.

Each certificate course will consist of two modules, the basic module which is an essential component of all the certificate courses and the relevant module of the applicant's choice. The minimum time required for completion of a certificate will be three months if the modules are taken concurrently. If the student chooses, the modules can be taken separately, in which case the two modules need to be completed in one year.

Credits can also be accumulated and all the modules completed along with a dissertation in three years for Masters.

### **MODULE: RESEARCH ETHICS**

#### **'ETHICS OF RESEARCH IN DEVELOPING COUNTRIES'**

Research is essential and integral for the scientific inquiry and necessary to remedies into ever increasing medical problems facing the world community. Human subjects are the vital component of that research and are an indispensable prerequisite. This introduces the potential for possible exploitation of the research subjects by placing them at risk of possible harm for the perceived benefit to others.

This module aims to discuss the essentials for making any human subjects research ethical. It examines different ethical issues raised by clinical trials, epidemiological studies and public health research especially in the context of developing countries. It discusses the issues of international

collaborative research involving human subjects in developing countries which raises different ethical issues that reflect the differences in standards of care, socio economic conditions and priorities of health care research. The fundamental issues remain the same of externally funded research about the ethics as it is understood in the west and problems it is facing in the east. The major differences are of religious and cross cultural values; stunted health care; conceptualization of autonomy; difficulties in realizing informed and voluntary consent, and the vulnerability of people with poor background. The module would encourage understanding and debating these issues in the context of developing countries. They would deliberate means and methods of minimising risk and maximising benefits for research subjects. The issue of conflict of interest will be discussed and the role of various stakeholders will be critically analysed by the students. The issues of scientific misconduct, intellectual property rights and plagiarism would be discussed.

The module would also examine various existing regional and international guidelines and codes for the ethical conduct of human research. These would be analysed and critiqued from the point of their local applicability and understanding how these documents could be made contextually relevant for developing countries, especially the Islamic world.

## Appendix III

### EDUCATING ETHICS COMMITTEES: EXPERIENCES FROM THE U.S.A.

#### 1. HEALTH CARE ETHICS COMMITTEES

Although Judith Wilson Ross and her colleagues published *Health Care Ethics Committees: The Next Generation* over a decade ago (1993 – American Hospital Publishing, Inc., Chicago, Illinois), Chapter 5, 'Education for Ethics Committees: What to Learn and How to Teach', contains a list of 17 'Bioethics Consensus Statements' that focuses on the decision-making authority of patients and reflects widely shared values. Here 'consensus' means virtual unanimity that a course of action is minimally acceptable to a particular community, e.g. the providers of health care. These consensus statements are worth repeating here, since at the time they were formulated, they already reflected the outcome of over two decades of discussions and publications among bioethicists and members of Health care / Hospital Ethics Committees established in numerous Member States. Though health care ethics is studded with controversy, these statements still attract general agreement. They also define the content of an educational programme for members of such committees.

#### 2. RESEARCH ETHICS COMMITTEES

The bioethics consensus statements that have emerged after two decades of the Health care / Hospital Ethics Committees movement focus on the dignity and decision-making authority of patients and their surrogates. Similarly, in the research ethics context, where healthy people as well as patients have agreed to participate, other consensus statements have emerged following more than a century of biological, biomedical, behavioural and epidemiological research.

1. The goals of research with human participants are to acquire generalizable knowledge to cure disease, restore function, eliminate suffering and prevent illness and injury.

2. All biological, biomedical, behavioural and epidemiological research must involve principal investigators, research participants and independent peer reviewers.

3. All biological, biomedical, behavioural and epidemiological research protocols must undergo review by a committee of institutional peers, including scientists, non-scientists, and lay representatives from the local community drawn from local, regional or national levels of government. This principle applies to research trials that are funded by one State, involves participants in a host State where the trial is conducted, and requires that two committees – one from each State – review the protocol.

4. The competent and informed potential participant has the right to refuse to participate in any research protocol or trial, at any time, regardless of his or her health status.

5. A diagnosis of mental illness does not by itself justify a judgement that the patient lacks decision-making capacity.

**6.** If a potential research participant is to provide researchers with his or her informed consent (children may provide their 'assent') and actually participate in a trial, he or she must have decision-making capacity, must act voluntarily, must be given adequate information about the research trial, e.g. its risks and benefits (usually benefits to others) that a reasonable person would need to have to make a decision to participate, must be able to comprehend the information, must know there will be no consequences regarding his or her health if he or she refuses to participate, and must not be coerced to participate in any way. Under specific conditions (that may require community approval and consent), and in accordance with domestic law and subject to the authorization and the protective conditions prescribed by law, research without the express individual consent of participants may be permitted.

**7.** No clinical trial should disadvantage, unfairly burden or exploit socially vulnerable persons, who may have inadequate power to negotiate with researchers, or who may be desperately ill and willing to consent to virtually any experimental intervention.

**8.** For a potential research participant to have decision-making capacity to agree to participate in a research trial, he or she must be able to understand the need for and purpose of the research, the alternatives that already exist (e.g. whether drugs, vaccines, surgical techniques or devices are already being marketed and prescribed for the disease under study), and must have the ability to relate the information to personal values and then freely communicate his or her decision.

**9.** The physician-scientist as researcher has a duty to inform a potential research participant that if he or she agrees to participate no personal benefit may accrue as a consequence of his or her participation. That is, participants must not mistakenly believe that the trial in which they have agreed to become involved will offer them direct personal, substantial clinical benefit.

**10.** The confidentiality of information obtained from research participants must be maintained in accordance with domestic law.

**11.** When a potential research participant (especially a seriously ill patient) refuses to participate in a clinical research trial and when all existing therapies have been tried and none have been effective, the physician-scientist researcher should understand the reasons for refusing, especially if the refusal will, in the researcher's judgement, lead to even more serious health consequences for the patient.

**12.** If a potential research participant lacks decision-making capacity, a family member or significant other may (within the existing regulatory framework) act as the potential participant's surrogate. The community may also serve as a surrogate decision-maker by advising on, or participating in, the design, approval and monitoring of the research trial.

**13.** If a potential research participant lacks decision-making capacity and his or her wishes about participating in research are known, they should be followed; if they are not known, an attempt should be made (e.g. by contacting family members) to determine what the person would probably have wanted. If that cannot be determined, the decision should be based on the patient's best interests as perceived by family and the physician-researcher; this is particularly relevant in emergency research, when a patient's views about participating in research are unavailable, and time is short.

**14.** Parents have a right to refuse or to approve requests to enter their children into research trials. Decisions should reflect the child's best interests, rather than the family's. Since benefits are more likely

to accrue to children who have not directly participated in the research (i.e. not to the children who participate in the trial), great care must be exerted by scientist-researchers to ensure that the children who participate are exposed only to minimal risk of harm.

15. Any apparent conflicts of interests on the part of a researcher should be addressed prior to the clinical trial.

## 2.1. The Clinical Investigation Program of the Institute of Health Professions at Massachusetts General Hospital –Boston, U.S.A

### Ethics and socially responsible clinical investigation

#### TOPICS

1. Schedule, Reading Assignments, Personal Journal, and Periodic Self-Evaluation.
2. The Term 'Human Subjects' Replaced by 'Human Participants'
3. The Imperative to Protect Animal and Human Research Participants: Ethical, Regulatory, and Scientific Design of Human Experimentation
4. Epistemological Presuppositions Involved in the Use of Human Beings in Research: 'Balancing' the Desire to Know against the Risks of Harms to and Safety of Animal and Human Participants
5. Protecting Animal and Human Participants:
  - A. The Use of Animals in Research
    - (i) Multiple criteria
    - (ii) The Three Rs: Replace, Reduce, and Refine.
  - B. The Early History of Human Experimentation
    - (i) Vivisection – Claude Bernard [1865]
    - (ii) Auto-Experimentation
6. Beginning at Nuremberg: The Doctors' Trials and *The Nuremberg Code* (1947) and Other International Documents:
  - A. World Medical Association, *Declaration of Helsinki* (adopted by the 18th World Medical Assembly – June, 1964), and amendments.
  - B. CIOMS / WHO, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (1993; revised 2002)
7. The Human Participants Protection System: The Research Ethics Committee Process:
  - A. Federal Regulations and the 'Common Rule'
  - B. Institutional Assurance
  - C. Principal Investigators
8. 'Balancing' Risks of Harms and Benefits:
  - A. Risks of Harms to and Benefits for Research Participants
  - B. The Conditions for Obtaining the Informed Consent from Potential Research Participants in Biomedical and Behavioural Research

9. Further Reflections on Participants' Informed Consent in Research:
  - A. Surrogate and Proxy Consent
  - B. The Therapeutic (Treatment) / Non-Therapeutic (Experiment) Distinction
  - C. The Bioethical Problem – Therapeutic Misconception
10. Informed Consent and the Research Ethics Committee:
  - A. Committee Documentation: The Informed Consent Form
  - B. Monitoring a Clinical Trial
11. The Equitable (or Just) Selection of Potential Participants of Epidemiological, Behavioural, and Biomedical Research: A Normative Process.
12. Vulnerable Groups Assured of Inclusion and Protection:
  - A. The elderly
  - B. Children – the Extrapolation Approach
  - C. Women of childbearing potential whose fetus may require special protection
13. Vulnerable Groups Assured of Inclusions and Protection (continued):
  - D. Cognitively impaired (mentally infirm) adults
  - E. Traumatized and comatose patients
  - F. Terminally ill patients
14. Vulnerable Groups Assured of Inclusion and Protection (continued):
  - G. Prisoners
  - H. Students, employees, normal volunteers
- I. International research: host and other States
15. Privacy and Confidentiality in Clinical Research:
  - A. Identifying Research Participants and Access to Their Information
  - B. Protecting Research Participants from Discrimination
16. Secrecy in Clinical Research:
  - A. Secrecy among Scientists Conducting Biomedical Research
  - B. The Principle of Disclosure Concerning Newly Acquired Knowledge
17. International Biomedical Research: External and Host States
  - A. Clinical Trials: Drugs, Vaccines, Surgeries, and Devices
  - B. Developing Medical-Technological Devices
18. Biomedical Research:
  - A. AIDS and HIV-Related Research
  - B. Transplantation Research
  - C. Human Genetic-Drug Research
19. Behavioural and Epidemiological Research
20. The Clinical Trial and Clinical Equipoise: Uncertainty and the Problem of Knowing Truly in Biomedical and Pharmaceutical Research:
  - A. Randomized Clinical Trials (RCT)
  - B. The Efficacy of 'Pilot' Trials
21. The Randomized Clinical Trial (RCT), the Quest for Certainty and the Safety

### UNDERSTANDING TRANSNATIONAL RESEARCH TRIALS - CONTINUING SELF-EDUCATION

1. Require collaborative review of protocols by host and funding State's Research Ethics Committees.
2. Address any barriers to obtaining potential participants' informed consent when soliciting and recruiting them from the host State.
3. Determine whether any unwarranted inducements are offered to persons from the host State who are solicited and recruited to participate in research trials.
4. Confirm whether potential research participants (and affected bystanders, e.g. relatives of participants in genetic trials) are (a) informed of and (b) understand any risks of harms, including 'minimal risks', they may encounter.
5. Clarify any present and/or future benefits that may accrue to persons in host States who participate in research trials – whether as individuals or members of communities.

for Research Participants:

- A. Safety Criteria for Terminating a Randomized Clinical Trial Participants' Legal and Other Remedies for Injury

#### 22. Problems with Randomizing Research Participants and Cohorts:

- A. Experimental Groups
- B. Control Groups
- C. Placebo Groups:
  - (i) Appropriate and Inappropriate Use (Deception) of Placebos
  - (ii) Placebos vs. the Placebo Effect: A Solution

#### 23. Protecting Research Participants in Emergency Circumstances – The Research Ethics Committee's Authority to Waive Informed Consent

#### 24. Waiving Informed Consent for Some Emergency Research Protocols

#### 25. Researchers' Potential Financial Conflicts of Interests

#### 26. Rules and Regulations for Conducting Ethical Research on Human Participants

#### 27. Course Review – What's Happened to Informed Consent in Human Experimentation? (The Incremental and Precarious Transition from Nuremberg Fundamentalism to Germ-Line Intervention and Future Persons)

#### 28. The Future of Protection Systems for Research Participants Committee Self-Evaluation

## 2.2. Research Ethics Program, University of California – San Diego, U.S.A.

### Responsible conduct of Research: Sustaining integrity and avoiding misconduct in research

#### TOPICS

1. Schedule, Reading Assignments, Personal Journal, and Periodic Self-Evaluation
2. Responsible Conduct of Research on Animals and Human Participants
3. Social and Ethical Responsibility
4. Sustaining Integrity in Research
5. Avoiding Misconduct in Research
6. Misconduct in Research
7. Reporting Allegations of Misconduct: Losing Public Confidence in Researcher
8. Official Channels
9. Whistle-blowing
10. Types of Misconduct
11. Data Management
12. Record keeping
13. Ownership of data
14. Sharing of data
15. Retention of data
16. Fabrication and Falsification of Data
17. Authorship
18. Plagiarism
19. Publication
20. Deception / Fraud
21. Peer Review / Bias
22. Mentoring / Exploitation
23. Collaborative Research / Collusion
24. Managing Competing Interests / Conflicts of Interests and Commitment
25. Investigating Allegations of Research Misconduct:
  - A. Conducting the Inquiry
  - B. The Investigation
  - C. Disciplinary Action
  - D. The Appeal Process
26. Special Topics:
  - A. Ethical Reasoning and Decision-Making
  - B. Environmental Health and Safety
  - C. Financial and Grants Management and Responsibility

**27. Special Topics (continued):**

**D. Maintaining Biosecurity during Bioterrorism**

**E. Genetic Information: Confidentiality and Privacy**

**F. Stem cell research: Bioethical Considerations**

**28. Committee Self-Evaluation:**

**A. Surveys as Tools for Education in Research Integrity**

**B. Questionnaires as Tools for Self-Evaluation**

## Appendix IV

### INTERNATIONAL BIOETHICS JOURNALS AND NEWSLETTERS

#### **Acta Bioethica**

Unidad de Bioética (IKM BIO – OPS/OMS)  
/ Bioethics Unit, Pan American Health  
Organization  
Avenida Providencia 1017, Piso 7,  
Providencia  
Casilla 61 – T,  
Santiago,  
Chile  
bioetica@chi.ops-oms.org  
<http://www.bioetica.ops-oms.org/E/public.htm>  
<http://www.paho.org/Spanish/BIO/publica.htm>  
ISSN: 0717-5906; 1726-569X (electronic)  
Portuguese; Spanish.

#### **American Journal of Bioethics**

MIT Press Journals  
Five Cambridge Center,  
Cambridge,  
Massachusetts 02142, U.S.A.  
[journals-orders@mit.edu](mailto:journals-orders@mit.edu)  
<http://bioethics.net>  
ISSN: 1526-5161  
English

#### **American Journal of Law and Medicine**

American Society of Law, Medicine & Ethics  
765 Commonwealth Avenue, Suite 1634  
Boston, Massachusetts 02215, U.S.A.  
<http://www.aslme.org/>  
ISSN: 0098-8588  
English

#### **Assia – Jewish Medical Ethics**

Schlesinger Institute,  
Shaare Zedek Medical Center  
P.O. Box 3235  
Jerusalem 91031,  
Israel  
[http://www.szmc.org.il/index.  
asp?id=97&top=1&page\\_id=212](http://www.szmc.org.il/index.asp?id=97&top=1&page_id=212)  
ISSN: 0334-3871  
English

#### **Bioethica Belgica**

Comité consultatif de bioéthique  
rue de l'Autonomie, 4  
1er étage - Bureau 109  
1070 Bruxelles, Belgium  
Contact: Mme Monique Bosson,  
Membership Secretary  
[monique.bosson@health.fgov.be](mailto:monique.bosson@health.fgov.be)  
<http://www.health.fgov.be/bioeth/>  
ISSN: none  
French

#### **Bioetica e Cultura**

Facolta Teologica de Sicilia,  
Istituto Siciliano di Bioetica,  
Corso Vittorio Emanuele, 463,  
90134 Palermo  
Italy  
<http://www.gte.it/isb/catalogo.html>  
ISSN: 1121-6948  
Italian

\* All websites were active on 20 October 2006

### **Bioètica & Debat**

Institut Borja de Bioètica  
bioetica@ibb.hsjdbcn.org  
<http://www.bioetica-debat.org/>  
ISSN: none  
Spanish

### **Bioetica: Revista Publicada Pelo Conselho Federal de Medicina**

Revista publicada pelo Conselho Federal de Medicina,  
Edifício Venancio 2000, Bloco B-50, salas 702/32  
Brasília DF CEP 70.333, Brazil  
<http://www.portalmedico.org.br/revista/bio1v8/revista.htm>  
ISSN: 0104-1401  
Portuguese

### **Bioethics**

Blackwell Publishing Journals  
Customer Services, P.O. Box 805,  
108 Cowley Road,  
Oxford OX4 1FH  
United Kingdom  
<http://www.blackwellpublishers.co.uk/>  
ISSN: 0269-9702  
English

### **Bioethics Bulletin**

Center for Clinical Ethics and Humanities  
in Health Care  
Veteran's Administration Medical Center,  
11th Floor  
3495 Bailey Avenue  
Buffalo, New York 14215 U.S.A.

<http://wings.buffalo.edu/faculty/research/bioethics/news.html>  
ISSN: none  
English

### **Bioethics Examiner**

Center for Bioethics  
University of Minnesota  
N504 Boynton, 410 Church Street SE  
Minneapolis, Minnesota 55455, U.S.A.  
bioethx@umn.edu  
<http://www.bioethics.umn.edu/publications/be.shtml>  
ISSN: none  
English

### **Biomedical Ethics: Newsletter of the European Network for Biomedical Ethics**

Interfakultäres Zentrum für Ethik in den  
Wissenschaften  
University of Tübingen  
Germany  
<http://www.izew.uni-tuebingen.de/>  
ISSN: 1430-9858  
English

### **BMC Medical Ethics**

BioMed Central Ltd  
Middlesex House,  
34-42 Cleveland Street,  
London W1T 4LB  
United Kingdom  
<http://www.biomedcentral.com/bmcmedethics/>  
ISSN: 1472-6939  
English

**Boletín: Instituto de Bioética de la Universidad Javeriana**

Instituto de Bioética - Cenalbe  
Pontificia Universidad Javeriana  
Transv. 4 No. 42-00 Piso 5  
Antiguo Instituto Neurológico, Bogota D.C.  
Colombia  
bioetica@javeriana.edu.co  
<http://www.javeriana.edu.co/bioetica>  
Spanish

**Bulletin Bibliographique ETHINSERM**

Institut National de la Santé  
et de la Recherche Médicale  
Le Centre de Documentation en Ethique  
des sciences de la vie et de la santé  
Faculté de médecine Necker  
156, rue de Vaugirard,  
75730 Paris - Cedex 15,  
France  
<http://www.euroethics.de/webcdei.htm>  
ISSN: 1144-4916  
French

**Bulletin of Medical Ethics**

Royal Society of Medicine Press Ltd.  
PO Box 9002  
London W1A 0ZA, United Kingdom  
<http://www.bullmedeth.info/>  
ISSN: 0269-1485  
English

**CQ: Cambridge Quarterly of Healthcare Ethics**

Cambridge University Press  
The Edinburgh Building

Shaftesbury Road  
Cambridge CB2 2RU,  
United Kingdom  
[journals@cambridge.org](mailto:journals@cambridge.org)  
<http://journals.cambridge.org/>  
ISSN: 0963-1801  
English

**Christian Bioethics**

Taylor and Francis  
4 Park Square, Milton Park  
Abingdon, Oxfordshire OX14 4RN  
United Kingdom  
[customerservice@taylorandfrancis.com](mailto:customerservice@taylorandfrancis.com)  
<http://www.taylorandfrancis.com>  
ISSN:1380-3603  
English

**Cuadernos de Bioética**

Viamonte 1450  
(1055) Buenos Aires  
Argentina  
[cuadernos@bioetica.org](mailto:cuadernos@bioetica.org)  
<http://www.bioetica.org>  
ISSN: 0328-8390  
Spanish

**Developing World Bioethics**

[official journal of the International  
Association of Bioethics]  
Blackwell Publishing  
United Kingdom  
<http://www.blackwellpublishing.com>  
ISSN: 1471-8731  
English

**Eidon: Revista de la Fundación de Ciencias de la Salud**

Fundación de Ciencias de la Salud  
Pza. Carlos Trías Bertrán, 4  
28020 Madrid,  
Spain  
<http://www.fcs.es/fcs/index.htm>  
ISSN: 1575-2143  
Spanish

**Ethics: An International Journal of Social, Political, and Legal Philosophy**

University of Chicago Press  
P.O. Box 37005  
Chicago, Illinois 60637, U.S.A.  
<http://www.journals.uchicago.edu/ET/>  
ISSN: 0014-1704  
English

**Ethics & Medicine: An International Journal of Bioethics**

The Bioethics Press  
PO Box 1032  
Highland Park, Illinois 60035,  
U.S.A.  
[info@bioethicspress.com](mailto:info@bioethicspress.com)  
<http://www.ethicsandmedicine.com/>  
ISSN: 0266-688X  
English

**Ethics and Behavior**

Lawrence Erlbaum Associates, Inc.  
10 Industrial Avenue  
Mahwah, New Jersey 07430-2262,  
U.S.A.

<https://www.erlbaum.com/>

ISSN: 1050-8422

English

**Ethics and Human Rights Issues Update**

[online journal]

Center for Ethics and Human Rights

American Nurses Association

8515 Georgia Avenue, Suite 400

Silver Spring, Maryland 20910, U.S.A.

[ethics@ana.org](mailto:ethics@ana.org)

[http://www.nursingworld.org/ethics/update/](http://www.nursingworld.org/ethics/update/uphome.htm)

[uphome.htm](http://www.nursingworld.org/ethics/update/uphome.htm)

ISSN: none

English

**Ethics and Medics**

The National Catholic Bioethics Center

6399 Drexel Road Philadelphia PA19151, U.S.A.

<http://www.ncbcenter.org/em/>

ISSN: 1071-3778

English

**Ethik in der Medizin**

Springer Publishing Group

International Home Page

<http://www.springeronline.com/sgw/cda/>

ISSN: 0935-7335

German

**Eubios Journal of Asian and International Bioethics** [online journal]

Asian Bioethics Association, and International  
Union of Biological Sciences Bioethics

Programme

RUSHSAP, UNESCO Bangkok  
920 Sukhumwit Road  
Prakanong, Bangkok  
Thailand 10110  
[http://www2.unescobkk.org/eubios/  
EJAIB.htm](http://www2.unescobkk.org/eubios/EJAIB.htm)  
ISSN:1173-2571  
English

**Formosan Journal of Medical Humanities**  
Chung Shan Medical & Dental College  
No. 110, Sec. 1, Chien-Kuo N. Road  
Taichung, China  
[medhuman@mercury.csmc.edu.tw](mailto:medhuman@mercury.csmc.edu.tw)  
[http://www.csmu.edu.tw/genedu/public\\_html/  
journal.htm](http://www.csmu.edu.tw/genedu/public_html/journal.htm)  
ISSN: 1606-5727  
English

**Hastings Center Report**  
The Hastings Center  
21 Malcolm Gordon Road  
Garrison, New York 10524-5555,  
U.S.A.  
[mail@thehastingscenter.org](mailto:mail@thehastingscenter.org)  
[http://www.thehastingscenter.org/publications/  
hcr/hcr.asp](http://www.thehastingscenter.org/publications/hcr/hcr.asp)  
ISSN: 0093-0334  
English

**Health and Human Rights: An International Journal**  
Francois-Xavier Bagnoud Center for Health and  
Human Rights  
Harvard School of Public Health

651 Huntington Avenue, 7th floor  
Boston, Massachusetts 02115,  
U.S.A.  
[fbxcenter@igc.org](mailto:fbxcenter@igc.org)  
[http://www.hsph.harvard.edu/fbxcenter/  
journal.htm](http://www.hsph.harvard.edu/fbxcenter/journal.htm)  
ISSN: 1079-0969  
English

**Health Care Analysis: An International Journal of Health Philosophy and Policy**  
Springer Publishing Group  
International Home Page  
<http://www.springeronline.com/sgw/cda/>  
ISSN: 1065-3058  
English

**Health Ethics Today**  
The Bioethics Centre, University of Alberta  
Edmonton, Alberta T6G 2J3  
Canada  
<http://www.ualberta.ca/BIOETHICS/page2.html>  
ISSN: none  
English

**HEC Forum (Healthcare Ethics Committee Forum)**  
Springer Publishers  
International Home Page  
P.O. Box 322, 3300 AH  
Dordrecht  
the Netherlands  
<http://www.springeronline.com/sgw/cda/>  
ISSN: 0956-2737  
English

**HREC: Bulletin of the Australian Health Ethics Committee**

Australian Health Ethics Committee (AHEC)  
MDP 100 - GPO Box 9848  
Canberra ACT 2601  
Australia  
ahec.nhmrc@nhmrc.gov.au  
<http://pandora.nla.gov.au/tep/31109>  
ISSN: none  
English

**Humane Health Care International**

[online journal]  
Multimed Inc.  
66 Martin Street  
Milton, Ontario L9T 2R2  
Canada  
<http://www.humanehealthcare.com/>  
ISSN: none  
English

**IDHL: International Digest of Health Legislation**

World Health Organization  
Geneva  
Switzerland  
idhl@who.int  
<http://www.who.int/idhl/>  
ISSN: none  
English; French.

**Indian Journal of Medical Ethics**

0-18, Bhavna, Veer Savarkar Marg,  
Prabhadevi, Mumbai 400025, India  
fme@vsnl.net

<http://www.issuesinmedicalethics.org>  
ISSN: none  
English

**Informationsbrief des DRZE**

Deutsches Referenzzentrum für Ethik in der  
Biowissenschaften  
Bonner Talweg 57  
53113 Bonn, Germany  
[http://www.drze.de/das\\_drze/infobrief.html](http://www.drze.de/das_drze/infobrief.html)  
German

**International Network on Feminist Approaches to Bioethics - Newsletter**

<http://www.fabnews.org/>  
ISSN: none  
English

**IRB: Ethics and Human Research**

The Hastings Center  
21 Malcolm Gordon Road  
Garrison, New York 10524-5555,  
U.S.A.  
mail@thehastingscenter.org  
<http://www.thehastingscenter.org/publications/irb/irb.asp>  
ISSN: 0193-7758  
English

**Itinerarium: Rivista Multidisciplinare dell'Istituto Teologico 'San Tommaso' Messina**

Itinerarium, Coop. S. Tom. a.r.l., P.I.  
01677650838  
Via del Pozzo 43, cas. post.  
28-98100 Messina, Italy

<http://www6.glauco.it/santommaso/itinerarium/>  
ISSN: 1127-3216  
Italian

**IWE: Institut für Wissenschaft und Ethik -Informationsbrief**  
Bonner Talweg 57  
53113 Bonn  
Germany  
<http://www.iwe.uni-bonn.de/>  
ISSN: none  
German

**Jahrbuch für Wissenschaft und Ethik**  
Institut für Wissenschaft und Ethik -  
Walter de Gruyter  
Genthiner Str. 13  
10785 Berlin,  
Germany  
<http://www.degruyter.de>  
ISSN: 1430-9017  
German

**Journal International de Bioethique**  
**International Journal of Bioethics**  
Editions ESKA  
12, rue du Quatre-Septembre  
75002 Paris,  
France  
Editions Alexandre Lacassagne  
162, avenue lacassagne  
69003 Lyon  
<http://www.eska.fr/site2001/revues/revue2jib.htm>

ISSN:1287-7352  
French; English

**Journal of Bioethical Inquiry**  
Bioethics Centre, University of Otago  
PO Box 913  
Dunedin  
New Zealand  
[editor@jbioethicalinquiry.org](mailto:editor@jbioethicalinquiry.org)  
<http://www.jbioethicalinquiry.org/>  
ISSN: 1175-3455  
English

**Journal of Clinical Ethics**  
138 West Washington Street, Suite 403  
Hagerstown, Maryland 21740, U.S.A.  
<http://www.clinicalethics.com/>  
ISSN:1046-7890  
English

**Journal of Law, Medicine & Ethics**  
American Society of Law, Medicine & Ethics  
765 Commonwealth Avenue, Suite 1634  
Boston, Massachusetts 02215, U.S.A.  
<http://www.aslme.org/>  
ISSN:1073-1105  
English

**Journal of Medical Ethics**  
BMJ Journals Department  
BMA House  
Tavistock Square  
London WC1H 9JR  
United Kingdom  
[jme@bmjgroup.com](mailto:jme@bmjgroup.com)

<http://jme.bmjournals.com/>

ISSN: 0306-6800

English

**Journal of Medical Humanities**

Human Sciences Press

233 Spring Street

New York, New York 10013-1578,

U.S.A.

ISSN: 1041-3545

English

**Journal of Medicine and Philosophy**

Taylor and Francis

4 Park Square, Milton Park

Abingdon, Oxfordshire OX14 4RN

United Kingdom

[customerservice@taylorandfrancis.com](mailto:customerservice@taylorandfrancis.com)

<http://www.taylorandfrancis.com>

ISSN: 0360-5310

English

**Journal of Philosophy, Science  
and Law** [online journal]

Georgia Institute of Technology

School of Public Policy

685 Cherry Street

Atlanta, Georgia 30332-0345, U.S.A.

<http://www.psljournal.com/>

ISSN: none

English

**Kennedy Institute of Ethics Journal**

Johns Hopkins University Press

2715 North Charles Street

Baltimore, Maryland 21218-4319,

U.S.A.

[http://www.press.jhu.edu/journals/](http://www.press.jhu.edu/journals/kennedy_institute_of_ethics_journal/)

[kennedy\\_institute\\_of\\_ethics\\_journal/](http://www.press.jhu.edu/journals/kennedy_institute_of_ethics_journal/)

ISSN: 1054-6863

English

**Lahey Clinic Medical Ethics Journal**

Lahey Hitchcock Medical Center

41 Mall Road, Box 541

Burlington, Massachusetts 01805,

U.S.A.

[http://www.lahey.org/NewsPubs/](http://www.lahey.org/NewsPubs/Publications/Ethics/index_menewsletter.asp)

[Publications/Ethics/index\\_menewsletter.asp](http://www.lahey.org/NewsPubs/Publications/Ethics/index_menewsletter.asp)

ISSN:1543-4672

English

**Medicina Conselho Federal**

Órgão Oficial do Conselho Federal de Medicina

Periodicidade Mensal

SGAS 915 Lote 72 - CEP: 70 390-150

Brasilia - DF,

Brazil

[jornal@cfm.org.br](mailto:jornal@cfm.org.br)

<http://www.cfm.org.br>

Portuguese

**Medicina e Morale**

Università Cattolica del Sacro Cuore

Largo F. Vito, 1

00168 Roma, Italy

[http://www.centrobioetica.org/med-morale/0-](http://www.centrobioetica.org/med-morale/0-med_mor.htm)

[med\\_mor.htm](http://www.centrobioetica.org/med-morale/0-med_mor.htm)

ISSN: 0025-7834

Italian

### **Medicina y Ética**

Facultad de Bioética  
Universidad Anáhuac  
Apartado Postal 10 844  
C.P. 11000  
México, D.F., Mexico  
egomez@anahuac.mx  
[http://www.anahuac.mx/bioetica/  
bibliografia.0.htm](http://www.anahuac.mx/bioetica/bibliografia.0.htm)  
ISSN: none  
Spanish

### **Medicine and Law: The World Association for Medical Law**

International Center for Health, Law and Ethics  
University of Haifa, Law Faculty  
PO Box 6451  
Haifa 31063,  
Israel  
<http://www.waml.ws/pages/medicine.asp>  
ISSN: 0723-1393  
English

### **Medicine, Health Care and Philosophy: A European Journal**

European Society for Philosophy  
of Medicine and Health Care  
Springer Publishing Group  
P.O. Box 322, 3300 AH  
Dordrecht  
The Netherlands  
<http://www.springeronline.com/sgw/cda/>  
ISSN: 1386-7423  
English

### **Medicinska Etika & Bioetika**

**Medical Ethics & Bioethics**  
Institute of Medical Ethics and Bioethics  
Limoba 12, 833 03  
Bratislava  
Slovakia  
ISSN: 1335-0560  
Slovak; English.

### **Monash Bioethics Review**

Centre for Human Bioethics  
Monash University  
Clayton, Victoria,  
Australia 3800  
Tel.: 61 3 990 54279  
[http://www.arts.monash.edu.au/bioethics/mbr.  
html](http://www.arts.monash.edu.au/bioethics/mbr.html)  
ISSN: 1321-2753  
English

### **National Catholic Bioethics Quarterly**

The National Catholic Bioethics Center  
6399 Drexel Road Philadelphia PA19151,  
U.S.A.  
<http://www.ncbcenter.org/ncbq.asp>  
ISSN: 1532-5490  
English

### **NCEHR Communiqué CNERH [online journal]**

National Council on Ethics  
in Human Research  
240 Catherine St., Suite 208  
Ottawa, Ontario K2P 2G8,  
Canada

office@ncehr-cnerh.org  
<http://www.ncehr.medical.org/english/communique.php>  
ISSN: 1181-8778  
French; English.

**Notizie de Politeia: Rivista di Etica e Scelte Pubbliche**

Via Cosimo del Fante  
13-20122 Milano,  
Italy  
[http://space.tin.it/scuola/flamusa/p\\_noti.htm](http://space.tin.it/scuola/flamusa/p_noti.htm)  
ISSN: 1128-2401  
Italian; English.

**Nursing Ethics**

Halifax, Nova Scotia,  
Canada  
<http://www.nursingethics.ca/>  
ISSN: 0969-7330  
English

**Persona y Bioética**

Campus Universitario Puente del Común  
Km 21 Autopista Norte de Bogotá  
Chía, Cundinamarca, Colombia  
[publicaciones@unisabana.edu.co](mailto:publicaciones@unisabana.edu.co)  
<http://gemma.unisabana.edu.co/publicaciones/revistas.asp>  
ISSN: 0123-3122  
Spanish

**Quirón**

Editorial Quirón  
Calle 508 entre 16 y 18

1897 M. B. Gonnet  
Pcia. de Buenos Aires, Argentina  
Spanish (with French and English summaries)

**Revista Romana De Bioetica**

The College of Physicians Iasi  
Carol I Street, no. 3-5  
Iasi, Romania  
[colegium@iasi.mednet.ro](mailto:colegium@iasi.mednet.ro)  
<http://www.bioetica.ro>  
ISSN: 1583-5170  
Romanian (some articles have English abstracts)

**Revista Latinoamericana de Bioética**

Universidad Militar 'Nueva Granada'  
Programa de Bioética  
Departamento de Educación, Humanidades  
Estudios  
Avanzados y Programas Especiales  
Carrera 11 No 101-80 Tercer piso, Torre  
Administrativa  
Bogotá, D. C. , Colombia  
[gcardona@santander.umng.edu.co](mailto:gcardona@santander.umng.edu.co);  
[revbio@santander.umng.edu.co](mailto:revbio@santander.umng.edu.co)  
<http://www.umng.edu.co/www/section-2469.jsp>  
ISSN: 1657-4702  
Spanish

**Revista Médica La Salle**

Escuela Mexicana de Medicina  
Calle Fuentes No. 31, Col.  
Tlalpan  
México, D.F. 14000, Mexico

<http://www.ulsamx.com>

ISSN: 1405-6763

Spanish

### **Revista Selecciones de Bioética**

Instituto de Bioética-Cenalbe

Transversal 4N 42-00 Piso 5

Pontificia Universidad Javeriana

Bogotá

Colombia

[bioetica@javeriana.edu.co](mailto:bioetica@javeriana.edu.co)

<http://www.javeriana.edu.co/bioetica>

ISSN: 1657-8856

Spanish

### **Revue de Presse en Ethique**

71, rue Saint-Dominique

75007 Paris

France

[contact@comite-ethique.fr](mailto:contact@comite-ethique.fr)

<http://www.ccne-ethique.fr/francais/start.htm>

ISSN: 1260-8599

French

### **Summa Bioética: órgano oficial de la Comisión Nacional de Bioética**

Antiguo Claustro del Hospital Juárez P/A

Plaza San Pablo

Centro. C.P. 06090

México, D.F.

Mexico

<http://bioetica.salud.gob.mx/>

ISSN: 1665-5303

Spanish

### **Theoretical Medicine and Bioethics**

Springer Publishing Group

P.O. Box 322, 3300 AH

Dordrecht, The Netherlands

<http://www.springeronline.com/sgw/cda/>

ISSN: 1386-7415

English

### **Vida y Etica**

Instituto de Bioética

Pontificia Universidad Católica Argentina

Av. Alicia M. De Justo 1400

C1107AFB-Buenos Aires

Argentina

[http://www2.uca.edu.ar/esp/sec-bioetica/esp/](http://www2.uca.edu.ar/esp/sec-bioetica/esp/page.php?subsec=publicaciones)

[page.php?subsec=publicaciones](http://www2.uca.edu.ar/esp/sec-bioetica/esp/page.php?subsec=publicaciones)

ISSN: 1515-6850

Spanish

### **Zeitschrift für Medizinische Ethik**

Schwabenverlag AG

Senefelderstrasse 12, D-7302

Ostfildern 1

Germany

<http://www.zfme.de/vs1/userseite/start.asp>

ISSN: none

German

## APPENDIX V

### INTERNATIONAL WEBSITES: FREE ACCESS TO FULL TEXT MATERIALS

**Site: Bioethics Home Page**

**Organization:** Council of Europe, Directorate of Legal Affairs, Bioethics Section

**Location:** Strasbourg

**Country:** France

[http://www.coe.int/T/E/Legal\\_affairs/Legal\\_cooperation/Bioethics/](http://www.coe.int/T/E/Legal_affairs/Legal_cooperation/Bioethics/)

**Description:** This online compendium of the Council of Europe's bioethics documents features *The Convention on Human Rights and Biomedicine* in English, French, German, Italian, Russian and Spanish, and includes historical documents relating to its development.

**Site: bioethics.net**

**Organization:** Center for Bioethics University of Pennsylvania

**Location:** Philadelphia, Pennsylvania

**Country:** U.S.A.

<http://www.bioethics.net/>

**Description:** In addition to hosting a blog on bioethical issues, the Center for Bioethics compiles relevant news items and provides links to documents on a wide range of topics including cultural diversity, cloning and conflict of interests.

**Site: bioethics.gov**

**Organization:** The President's Council on Bioethics

**Location:** Washington, District of Columbia

**Country:** U.S.A.

<http://bioethics.gov/>

**Description:** In addition to being a repository for the Council's reports, this site includes the full text of numerous articles and book chapters used in the production of the reports.

**Site: Bioethics Resources on the Web**

**Organization:** NIH Inter-Institute Bioethics Interest Group, National Institutes of Health

**Location:** Bethesda, Maryland

**Country:** U.S.A.

<http://www.nih.gov/sigs/bioethics/index.html>

**Description:** This site focuses on guidance for research design and implementation.

**Site: Bioéthique**

**Bioethics**

**Organization:** UNESCO Bioethics Programme

**Location:** Paris

**Country:** France

<http://www.unesco.org/shs/bioethics>

**Description:** This site contains texts in English and French on international bioethics issues, a guide to establishing Bioethics Committees, and reports on such topics as cloning and women's rights.

**Site: Bioética**

**Organization:** Organización Panamericana de la Salud / Pan American Health Organization

\* All websites were active on 20 October 2006

**Location:** Washington, District of Columbia

**Country:** U.S.A.

<http://www.paho.org/Spanish/bio/home.htm>

**Description:** This site provides access to full text handbooks, manuals and journals, as well as to a virtual bioethics library.

**Site: Bioética.org**

**Organization:** Cuadernos de Bioética

**Location:** Buenos Aires

**Country:** Argentina

<http://www.bioetica.org>

**Description:** In addition to being the repository for the online journal *Cuadernos de Bioética*, this site contains links to bioethics-related legislation from Latin and South American countries and to articles from the newsletters of bioethics organizations.

**Site: Center for Ethics & Professionalism**

**Organization:** American College of Physicians

**Location:** Philadelphia, Pennsylvania

**Country:** U.S.A.

<http://www.acponline.org/ethics/>

**Description:** This site features the full text of the American College of Physicians' *Ethics Manual* in both English and Spanish, ethics case studies, position statements, and a collection of articles on end-of-life care.

**Site: Codex**

**Organization:** The Swedish Research Council

**Location:** The Centre for Bioethics at

Karolinska Institute, Stockholm and Uppsala University, Uppsala

**Country:** Sweden

[http://www.codex.uu.se/codex\\_eng/codex/index.html](http://www.codex.uu.se/codex_eng/codex/index.html)

**Description:** This website contains links to research ethics guidelines and topical systematic summaries.

**Site: Comité Consultatif National d'Ethique National Consultative Bioethics Committee**

**Organization:** Comité Consultatif National d'Ethique

**Location:** Paris

**Country:** France

<http://www.ccne-ethique.fr/>

**Description:** CCNE's opinions are available on this site along with links to other ethics advisory committees.

**Site: DRZE**

**Organization:** Deutsches Referenzzentrum für Ethik in den Biowissenschaften

German Reference Centre for Ethics in the Life Sciences

**Location:** Bonn

**Country:** Germany

<http://www.drze.de/>

**Description:** In addition to a number of full text publications on bioethical issues, DRZE features a bioethics database searchable with a multilingual thesaurus in English, French and German.

**Site: Ethics Updates**

**Organization:** Values Institute, University of San Diego

**Location:** San Diego, California

**Country:** U.S.A.

<http://ethics.acusd.edu/>

**Description:** Edited by philosophy professor Lawrence M. Hinman, this site contains articles and videos on ethical theories and bioethical issues organized by topic.

**Site: Groupe Européen d’Ethique des Sciences et des Nouvelles Technologies  
European Group on Ethics in Science and New Technologies**

**Organization:** Commission européenne / European Commission

**Location:** Brussels

**Country:** Belgium

[http://ec.europa.eu/european\\_group\\_ethics/](http://ec.europa.eu/european_group_ethics/)

**Description:** This site contains the opinions of the GEE, and full text publications in English and French on a wide range of ethical issues with biotechnology.

**Site: National Bioethics Advisory Commission**

**Organization:** National Bioethics Advisory Commission (NBAC) (defunct)

**Location:** Rockville, Maryland

**Country:** U.S.A.

<http://bioethics.georgetown.edu/nbac/>

**Description:** This repository of NBAC reports and meeting transcripts features such topics as *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (2001), and *Ethical Issues in Human Stem Cell Research* (1999).

**Site: National Reference Center for Bioethics Literature (NRCBL)**

**Organization:** Kennedy Institute of Ethics, Georgetown University

**Location:** Washington, District of Columbia

**Country:** U.S.A.

<http://bioethics.georgetown.edu>

**Description:** Through its Digital Collection Project, this site provides access to historical reports in bioethics and *Scope Notes* on bioethical issues such as *Vulnerability*,

*Vulnerable Populations, and Policy*, and *Bioethics, Biolaw, and Western Legal Heritage*. Other full text publications can be accessed by searching NRCBL’s database, ETHX on the Web, and limiting the search to online materials.

**Site: Nuffield Council on Bioethics**

**Organization:** Nuffield Council on Bioethics

**Location:** London

**Country:** U.K.

<http://www.nuffieldbioethics.org/>

**Description:** The Council’s reports and discussion papers are posted on this site, including *The Ethics of Research Related to Healthcare in Developing Countries* which is available in French and Spanish in addition to English.

**Site: onlineethics.org**

**Organization:** Online Ethics Center for Engineering and Science, Case Western Reserve University

**Location:** Cleveland, Ohio

**Country:** U.S.A.

<http://onlineethics.org/index.html>

**Description:** This site contains research ethics resources and provides a Spanish index to the materials. An Ethics Help-Line feature enables scientists to request individual guidance when facing an ethical problem.

**Site: SciDev.net**

**Organization:** Science and Development Network

**Location:** London

**Country:** U.K.

<http://www.scidev.net/>

**Description:** Dedicated to facilitating access to scientific and technical information for

developing countries, this site includes a research ethics dossier featuring news items and articles from both peer-reviewed journals and Science and Development Network correspondents.

**Site: UNESCO**

**Organization:** United National Educational, Scientific and Cultural Organization

**Location:** Paris

**Country:** France

<http://www.unesco.org/shs/ethics>

**Description:** UNESCO's programme in this area addresses ethics of science and technology, in particular bioethics. It aims to strengthen the ethical link between scientific advancement and the cultural, legal, philosophical and religious context in which it occurs. UNESCO's strategy in this area is to act as a standard-setter on emerging ethical issues, to disseminate information and knowledge and to help Member States build their human and institutional capacities.

**Site: WHO Ethics**

**Organization:** World Health Organization

**Location:** Geneva

**Country:** Switzerland

<http://www.who.int/ethics/en/>

**Description:** This site has been created as an

aid to persons, both inside and outside of WHO, seeking information about bioethics, including the ethical aspects of health care delivery and planning as well as the ethics of clinical care, research and biotechnology. It provides a global calendar of bioethics events, resources on research ethics and information about a range of topics in ethics.

**Site: WMA Ethics**

**Organization:** World Medical Association

**Location:** Ferney-Voltaire

**Country:** France

<http://www.wma.net/e/ethicsunit/index.htm>

**Description:** Since its foundation in 1947, the WMA's main goal has been to establish and promote the highest possible standards of ethical behaviour and care by physicians. In pursuit of this goal it has adopted policy statements on a large number of ethical issues related to medical professionalism, patient care, research on human subjects and public policies. The Ethics Unit will help the WMA Council and standing committees review and update current policies and develop new ones on emerging ethical issues. It will also serve as a clearinghouse of ethics information resources for national medical associations, their physician members and other interested parties and will develop new resources as appropriate.

## APPENDIX VI

### UNESCO PUBLICATIONS: FREE ONLINE ACCESS

All UNESCO publications are in general available in the six official languages of the Organization: Arabic, Chinese, English, French, Russian and Spanish.

#### 1. BIOETHICS

*The Universal Declaration on the Human Genome and Human Rights*. Paris, France, 1997.  
[http://portal.unesco.org/en/ev.php-URL\\_ID=13177&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html)

*International Declaration on Human Genetic Data*. Paris, France, 2003.  
<http://unesdoc.unesco.org/images/0013/001361/136112e.pdf>

*Bioethics. International Implications*. Paris, France, 2003.  
<http://unesdoc.unesco.org/images/0013/001309/130976e.pdf>

*Human Cloning. Ethical issues*. Paris, France, 2004.  
<http://unesdoc.unesco.org/images/0013/001359/135928e.pdf>

*Universal Declaration on Bioethics and Human Rights*, Paris, France, 2005.  
<http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>

*Establishing Bioethics Committees (Guide No. 1)*, Paris, France, 2005.  
<http://unesdoc.unesco.org/images/0013/001393/139309e.pdf>

*Bioethics Committees at Work: Procedures and Policies (Guide No. 2)*, Paris, France, 2006.  
<http://unesdoc.unesco.org/images/0014/001473/147392e.pdf>

*Bioethics. Questions and answers* [only in Russian]. Moscow, Russian Federation, 2006.  
<http://www.unesco.ru/files/docs/shs/Bioethics%20brochure.pdf>

#### 2. ENVIRONMENTAL ETHICS

*The ethics of energy*. COMEST (Jean Audouze). Paris, France, 1997.  
<http://unesdoc.unesco.org/images/0011/001132/113233E.pdf>

*Best ethical practices in water use*. Paris, France, 2004.  
<http://unesdoc.unesco.org/images/0013/001344/134430e.pdf>

***Water and ethics. Institutional issues.*** Paris, France, 2004.  
<http://unesdoc.unesco.org/images/0013/001363/136353e.pdf>

***The Precautionary Principle,*** World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), Paris, France, March, 2005.  
<http://unesdoc.unesco.org/images/0013/001395/139578e.pdf>

### 3. SCIENCE ETHICS

***Avicenna and the ethics of science and technology today.*** Paris, France, 2004.  
<http://unesdoc.unesco.org/images/0013/001344/134475e.pdf>

***Ethics of Science and Technology. Explorations on the frontiers of science and ethics.*** Paris, France, 2006  
<http://unesdoc.unesco.org/images/0014/001454/145409e.pdf>

***The Teaching of Ethics,*** World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), Paris, France 2004.  
<http://unesdoc.unesco.org/images/0013/001345/134552mb.pdf>

***Declaration on Science and the Use of Scientific Knowledge,*** World Conference on Science for the Twenty-First Century: A New Commitment (Budapest, Hungary 26 June to 1 July 1999). [UNESCO and ICSU - International Council of Scientific Unions, 1 July 1999]  
<http://unesdoc.unesco.org/images/0012/001229/122938eo.pdf>

***Towards Knowledge Societies,*** UNESCO World Report, Paris, France, 2005.  
<http://unesdoc.unesco.org/images/0014/001418/141843e.pdf>  
[ISBN 92-3 204000-X]

### 4. TECHNOLOGY ETHICS

***The ethics of space policy.*** COMEST (Alain Pompidou), Paris, France, 2000.  
<http://unesdoc.unesco.org/images/0012/001206/120681e.pdf>

***Legal and ethical framework for astronauts in space sojourns.*** Paris, France, 2005.  
<http://unesdoc.unesco.org/images/0013/001397/139752m.pdf>

***The ethics and politics of nanotechnology.*** Paris, France, 2006.  
<http://unesdoc.unesco.org/images/0014/001459/145951e.pdf>

## Division of Ethics of Science and Technology of UNESCO

The Division of Ethics of Science and Technology reflects the priority UNESCO gives to ethics of science and technology, with emphasis on bioethics. One objective of the medium-term strategy of the Organization is to "promote principles and ethical norms to guide scientific and technological development and social transformation".

Activities of the Division include providing support for Members States of UNESCO that are planning to develop activities in the field of ethics of science and technology, such as teaching programmes, national ethics committees, conferences and UNESCO Chairs.

The Division also ensures the executive secretariat for three international ethics bodies, namely the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC).

UNESCO  
Division of Ethics of Science and Technology  
Social and Human Sciences Sector  
1, rue Miollis  
75732 Paris Cedex 15  
France  
<http://www.unesco.org/shs/ethics>

