Guide No.2

Bioethics Committees at Work: Procedures and Policies

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

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FOREWORD

This Guide, like Guide No.1, is intended to provide precisely what its title denotes: guidance. Guide No. 2 neither proffers a mere collection of internal procedures and policies nor advocates that Bioethics Committees adopt a particular set of procedures and policies to guide them when they convene. However, Guide No. 2 suggests that chairpersons and members of the four established forms of Bioethics Committees consider and evaluate certain procedures and policies to guide them in fulfilling their mandates. If requested, the Division of Ethics of Science and Technology of UNESCO can provide advice and consultation with respect to the procedures and policies that have already been successfully adopted by Bioethics Committees and that, when consistently followed over time, have served the Committees well in carrying out their general mandates and achieving their particular objectives.

Guide No. 1 noted the different goals of Bioethics Committees, namely:

1. to establish sound science and health policies for Member States' citizens;
2. to establish sound professional practices for patient care;
3. to improve patient-centred care; and
4. to protect human research participants while acquiring generalizable biological/biomedical, behavioural and epidemiological knowledge.

There are, however, a few additional features that have led to significant achievements by Bioethics Committees: they have worked concretely to influence others to respect human dignity; they have become instruments of fairness and justice; and they have enhanced human values, bearing in mind that these values, norms or preferences may vary among Member States. Moreover, the establishment of these Committees has widened the base of bioethical discussions. Today, an individual scientist or researcher, for example, is often not the sole voice of authority in decision-making when conducting clinical trials. Bioethics Committees' chairpersons and members also contribute their perceptions concerning the resolution of bioethical problems when they convene with health professionals, biologists, behavioural scientists and others, including lay Committee members.

In 1991, UNESCO's Division of Human Rights, Democracy, Peace and Tolerance sponsored an International Meeting on Bioethics and the Social Consequences of Biomedical Research. In the unpublished *Final Report and Recommendations* of this meeting, the Rapporteur noted that '…hospital ethics committees are the most prevalent response to bioethics, providing education, consultation, and policy development'. He was specifically referring to Hospital (now more broadly called Health Care) Ethics Committees and other health care institutions' Ethics Committees as well, such as those established in inpatient clinics, long-term care institutions and hospices. The Rapporteur at the meeting did not mention

Policy-Making and/or Advisory Bioethics Committees, already established at the national level of a number of Member States' governments, or Health-Professional Association Bioethics Committees, organized within health-professional associations. The meeting's discussions did cross the ambiguous boundary between Health Care Ethics Committees and Research Ethics Committees. This was evident from the meeting's agenda, which included a few procedural and policy issues, in addition to presentations on and discussions about substantive bioethical issues such as the surgical transplantation of human organs from living or cadaver donors to awaiting recipient patients, the equitable distribution of these organs and tissues among recipients and the ethically worrisome commercialization of human organs. In the meeting's *Final Report*, the Rapporteur underscored the point that 'there is no agreement on procedural matters: (1) Whom should the Committees serve? (2) Who should be on the Committees? (3) What topics should they cover? (4) What is the extent of their authority?' He concluded, 'These procedural issues must be identified early and agreement reached; otherwise these Committees will fail'.

Guide No.1 addressed, albeit briefly, these four procedural questions, but a number of other procedures and policies are discussed in the present *Guide*. We are grateful to Emeritus Professor Stuart F. Spicker, founding co-editor of the book series, *Philosophy and Medicine*, for his support in structuring and preparing this *Guide*. Finally, UNESCO's Division of Ethics of Science and Technology can assist in fostering cooperation among the established Bioethics Committees of UNESCO's Member States, since it is increasingly important that we no longer disregard the salient internal procedures and policies that serve to maintain the continuity and overall effectiveness of working Bioethics Committees. Hence this *Guide No. 2* is entitled *Bioethics Committees at Work: Procedures and Policies.*

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INTRODUCTION

Bioethics Committees are most effective when their incorporation into government is statutory (see Guide No. 1, Appendix 2, pp. 66-72) because this grants them a stability and legitimacy that add immeasurably to their stature. Committees are likely to achieve this goal when their Member States meet three preconditions: first, that they respect human rights and advocate and support the freedom of individuals, particularly vulnerable patients and volunteers who participate in clinical research trials principally to benefit future patients; second, that they acknowledge the dignity of patients and those persons – healthy or ill – who participate in biological/biomedical, behavioural and epidemiological research trials; and third, that they sustain educational programmes in bioethics for present and future chairpersons and members of the various forms of Bioethics Committees (see preconditions set out below).

PRECONDITIONS FOR BIOETHICS COMMITTEES

Bioethics Committees should:
- respect human rights;
- acknowledge the dignity of citizens;
- sustain educational programmes in bioethics.

All four forms of Bioethics Committees in pluralistic societies are founded on the premise that all persons with mental capacity, or their proxies, are moral agents and that the chairpersons and members of these Committees, themselves moral agents, are obliged, not simply entitled, to speak to bioethical controversies and particularly contentious issues and dilemmas that arise in the day-to-day activities of policy and advisory boards at the national level of government, in health-professional associations, in hospitals and other health care institutions, and in clinical research centres.

FOUR FORMS OF BIOETHICS COMMITTEES

- Policy-Making and/or Advisory Committee
- Health-Professional Association Committee
- Health Care/Hospital Ethics Committee
- Research Ethics Committee

The first two forms of Bioethics Committee do not tend to create confusion. Policy-Making and/or Advisory Committees focus on providing advice to government officials and hope to influence the adoption of science and health policies at the national level of

government. Health-Professional Association Committees address bioethical issues for health care professionals (physicians, nurses, pharmacists or other allied health professionals). There is, however, a tendency to combine problems to be discussed by Health Care Ethics Committees, which address clinical practice involving patients, with problems for consideration by Research Ethics Committees, which review research protocols involving the participation of human beings. Such combination of problems may lead to the joint consideration of issues that are perhaps best considered separately. To clarify, Health Care Ethics Committees primarily discuss patient-care issues whereas Research Ethics Committees address the scientific merits, the risk of harms to research participants and the possible benefits that might accrue to future patients who did not themselves participate as 'subjects' in the clinical trials. Some Bioethics Committees perform both functions, though the evidence to date suggests that this combined model has not proven very successful.

The decision to establish new Committees is driven by a number of factors, not least of which is the need – now recognized by scientists, health professionals, and many others – to share in deliberating complex bioethical issues not only with colleagues (life scientists and various health specialists) but also with other stakeholders, including the media and the public. Here, it is important to recognize what has occurred in the field of bioethics since the late 1960s: bioethical issues, including complex cases and dilemmas, are no longer left for bioethicists alone to analyse. Indeed, Bioethics Committees in any of the four forms may each have only one or possibly two members who have competence in bioethics, having received advanced degrees in bioethics and worked in research and health care settings. In short, although today's Bioethics Committees' deliberations focus on bioethics, they are not solely addressed by bioethicists; in fact, bioethicists who serve on Bioethics Committees are always in the minority.

As early as 1974, UNESCO prepared a document, *Recommendations on the Status of Scientific Researchers*, which was adopted by its Member States. This document, though it has only persuasive and not mandatory authority, reflects the view that governments worldwide have recognized that scientists, health care practitioners and professional researchers must not only uphold patients' and research participants' rights but also fulfil their own corresponding responsibilities to them. UNESCO affirmed that bioethical, not merely biotechnical, values must take priority; that humanity takes precedence over scientific and biotechnological achievements, however awesome and potentially transformative of societies these achievements may be. Evidence for this is the fact that many Member States have established Policy-Making and/or Advisory Bioethics Committees at the national level of government (see *Guide No. 1 – Establishing Bioethics Committees,* Appendix 1, pp. 62-65).

It should be stressed, lest there be misunderstanding, that Bioethics Committees,

particularly those established in pluralistic societies, need not always seek moral consensus as a goal of their discourse and deliberations. Though some bioethicists clearly have competence, if not expertise, the best approach is for everyone involved to remain modest and appreciate the fact that Bioethics Committees may well prove to be the most appropriate venues for continuing these conversations in the future. Each type of Committee will generate discussions and analyses specific to their distinctive goals (as set out below).

GOALS OF THE DIFFERENT KINDS OF BIOETHICS COMMITTEES

1. Policy-Making and/or Advisory Committees: establish sound science and health policies for Member States' citizens (public health, well-being and rights)
2. Health-Professional Association Committees: establish sound professional practices for patient care (physicians, nurses, pharmacists and allied health professionals)
3. Health Care Ethics Committees: improve patient-centred care (hospitals, outpatient clinics, long-term care institutions, hospices)
4. Research Ethics Committees: protect human research participants while acquiring generalizable biological/biomedical, behavioural and epidemiological knowledge (pharmaceuticals, vaccines, devices)

Policy-Making and/or Advisory Committees will focus on science and health policy at the national level. Health-Professional Association Committees will concern themselves with proper standards and practices for their respective professions. Health Care Ethics Committees will target policies that directly affect the care of patients. Research Ethics Committees will attend to the interests of human participants in clinical trials. The Committees will thus exhibit a specialization of functions and a division of labour, which will be reflected in their discourse.

Part I

BIOETHICS COMMITTEES AS PLATFORMS FOR DELIBERATIONS AND POLICY RECOMMENDATIONS

1. Reviewing the four forms of Bioethics Committees

1.1. Policy-Making and/or Advisory Committees

Policy-Making and/or Advisory Committees do not usually have political power; rather, they engage in discourse to inform and persuade government officials and the public. When such a Committee is established by a Member State, it is usually charged with advising the Head of State and other government officials – particularly those who serve as ministers of science and technology and members of their staff – on bioethical issues, especially those that are anticipated to require the formation of new government policies. These Committees serve as platforms for deliberation not only on general bioethical issues, but also on particular dilemmas raised as a consequence of advances in the biological/biomedical and behavioural sciences and biotechnology. They tend to focus on bioethical issues that have recently emerged or are soon expected to receive the attention of the media and the public.

Some Bioethics Committees established at the national level of government address only those bioethical issues that arise in planning and conducting clinical investigations in which human beings are needed as participants. Having consented to participate in clinical research trials, the participants deserve and also often receive their government's protection from serious risk of harms, especially since they are volunteers – healthy or ill. This protection typically takes the form of regulations governing the researchers' procedures.

Although some of these Committees function at the national level of government, they are actually Research Ethics Committees usually established and convened at local government level. At the national level, however, they bear such titles as: 'National Advisory Board on Research Ethics', 'National Ethics Committee for Clinical Investigation', 'Committee of Bioethics – National Committee for Research Ethics in Science and Technology', 'National Committee for Medical Research Ethics', 'Medical Research Council Ethics Committee', and 'Health Research Council Ethics Committee' (see *Guide No. 1 – Establishing Bioethics Committees,* Appendix 1, pp. 62-65).

1.2. Health-Professional Association Committees

Scientists and health professionals, like other professionals, in virtually all Member States, have established associations whose purpose is to advance and defend the interests of their profession. The leaders of these national associations usually follow previously adopted procedures for accepting new applications for

membership, normally requiring relevant credentials like advanced degrees. The leaders of Health-Professional Association Bioethics Committees – associations of physicians, nurses, pharmacists, or other allied health professionals – have recently discovered that their members have found themselves obliged to address an increasing number of bioethical issues, some of which have attracted considerable public attention. With the strands of globalization tying the world together, a bioethical issue – even one patient's case – in one Member State may easily trigger discussion and debate throughout the world in a matter of days or even hours via television and the Internet. Health-Professional Association Committees, therefore, have typically resorted to creating subcommittees whose tasks are to address these bioethical issues, prepare reports, submit them to the entire Committee for review and approval and, in time, distribute these reports to the Committee for further deliberation and approval.

The chairperson of this form of Committee usually appoints the members of the subcommittees – between five and twelve members. Most of these Bioethics Committees include a few members who are not formally educated in the particular specialty that defines the group, but they represent related interests. It is not unusual for members to serve an average of four years, but there is usually no single policy that defines members' tenure. As is the case for most Bioethics Committees, Health-Professional Association Committees tend to meet on a regular rather than on an ad hoc basis, and may convene monthly or bi-monthly. In addition, these Committees often conduct annual conferences as well as periodic workshops and seminars, typically focusing on bioethical issues that are faced by the profession. Outside consultants may also be invited to share their views. In addition, Health-Professional Association Committees produce and distribute publications, scholarly papers, and summary (sometimes consensus) statements on various bioethical topics and issues.

Finally, Health-Professional Association Committees tend to adopt and disseminate ethical standards for all the members of the Committee. This is a complex and time-consuming task, and may require a number of consultations with various experts, including those who specialize in organizational ethics, since a profession's ethical standards will affect all the members of the association. Owing in part to the fact that Health-Professional Association Committees are generally homogeneous – essentially composed of members proficient in the same profession – less is known about this form of Bioethics Committee and the specific bioethical issues they address. Moreover, the extent of Health-Professional Association Committees' influence on their individual members is far from clear. Further study of these national Committees in terms of their bioethics activities is long overdue. Nevertheless, it is clear that Health-Professional Association Committees are making efforts to address the bioethical issues that confront their professions. To do so effectively, however, they, like the other forms of Bioethics Committees, will need to pay closer attention not only to substantive bioethical issues but also to their own internal procedures and policies.

1.3. Health Care Ethics Committees

Although Health Care Ethics Committees continue to increase in number in many Member States, they are not yet established in all Member States. As new Committees are established, the practice of what has been dubbed 'patient-centred care' – a term of recent origin – will appear somewhat novel. This expression actually serves to camouflage the rather recent change of attitude among health professionals towards their patients and towards patients and healthy persons who have consented to participate in clinical research trials.

When Health Care Ethics Committees convene they usually seek to determine whether the patient or his or her family members have been offered the opportunity to voice their views. Health professionals need not necessarily comply with patients' or their families' demands, although in many Member States patients and their proxies have a compelling voice when it comes to accepting or refusing medical treatment. Hence 'patient-centred care' is nothing short of respecting each patient's dignity – acknowledging a competent patient's autonomous choice to participate in his or her treatment and care decisions and, as noted, to accept or reject them in advance. Here it is worth noting that autonomy usually indicates a form of personal liberty of action where each individual determines not only his or her own plan of action in cooperation with health professionals, but also a willingness to accept or refuse medical treatment, especially arduous and burdensome treatment.

The slow transition to patient-centred care has directly affected not only the Health Care Ethics Committee movement and the continuing establishment of these Committees, but also the formulation of the Committees' recommended internal policies and guidelines, that are passed on by Committees for approval to the administration of the health care institutions in which they are situated. For example, Health Care Ethics Committees have frequently either been called upon to take, or have taken, a proactive role in formulating or amending existing Do-Not-Resuscitate (DNR) policies in their health care institutions.

For a Health Care Ethics Committee to evaluate its influence and effectiveness over guidelines and DNR policy development, it may prove useful to review its recommendations to determine precisely what policies it has succeeded in having its health care institution adopt. But such a review may at times be a misleading indicator of the Health Care Ethics Committee's actual influence on policy and guideline development. Sometimes the Committee may recommend a new policy, a revision of current policy, or perhaps the maintenance of current policy without changes. With respect to formulating a DNR policy, a number of Health Care Ethics Committees have discovered that the present policy is perfectly adequate and requires no modification. On the other hand, it is also possible that new or revised guidelines and policies could have very positive effects within the health care institution; nor need they be detrimental to the institution's broader objectives.

Simply to enumerate the policies and guidelines a Health Care Ethics Committee has

implemented could easily lead to overestimation of its performance and effectiveness. Research on the influence of Health Care Ethics Committees indicates that the most significant indicators of their success are (1) the seniority of the Committees, that is, the length of service of their members and (2) the frequency of meetings, that is, whether the Committee convenes more than once a month.

None of this, of course, speaks to the question of whether a Health Care Ethics Committee's influence is for good or ill. It may, after all, succeed in causing its health care institution to do the wrong thing, which is to say, to adopt an unworkable and unethical procedure.

Recognition of this may induce a sense of humility so that the Health Care Ethics Committee acknowledges that its deliberations and recommendations are, like all human contrivances, prone to error. Intelligence, experience, hard work, consistency with the past – none of these should be an excuse for closed-mindedness, complacency, or the conviction that the issue has been settled for all time and requires no re-examination. This is a constant temptation because it saves time and work and avoids controversy, but the Committee, especially its chairperson, must constantly be on guard to combat it. In short, Health Care Ethics Committees' policy formulations should be assessed in terms of how they actually affect clinical practice. How often do the results of committees' efforts simply appear in writing and disappear unread and unimplemented, failing therefore to have any bearing on clinical practice?

To be sure, this failing would certainly become visible following a formal, or even an informal, process of evaluation of an Health Care Ethics Committee's effectiveness. The only conceivable way to avoid this failing is for a Committee to begin to educate, in detail, the entire staff of the institution about any new guidelines or policies it adopts, such as a new or revised DNR policy.

Here a word of caution is in order: Even the most clearly stated policy might not serve to establish a single course of action for all patients' cases or situations. A Health Care Ethics Committee might adopt another policy: not to encourage, even to discourage, hospital staff from taking the Committee's previous case reviews and recommendations as being carved in stone simply because those recommendations may have been consistent over time with respect to numerous case reviews. The outsider would be incorrect to presume that the Committee's recommendations on previous cases could necessarily be applied to other cases.

1.4. Research Ethics Committees

When international interest in the bioethical issues surrounding human research emerged following the Nuremberg trials (1946), attention was focused on striking a balance between the virtually unchallenged freedom of physician-scientists to pursue their clinical investigations and the protection of individuals who had consented to serve as subjects in these clinical experiments, investigations, trials or studies.

Indeed, 'subjects' now bears a somewhat pejorative connotation: it is received as denoting a dehumanized view of human beings in which they are merely means to an end. Hence, the terms 'persons', 'participants', or 'study participants' have typically replaced 'subjects' in the extant literature. It is frequently stated in declarations and ethical codes that clinical researchers are obliged to protect the dignity, identity and integrity of each person who participates in any research protocol.

Research Ethics Committees, as has been noted, have not only been established at the local and regional levels of government, but many now exist at the national level as well. They have all adopted internal review procedures and policies for developing, revising, implementing and, if adequate resources are available, even monitoring the implementation of their general guidelines and regulations by those conducting clinical investigations in various research centres. Each Research Ethics Committee is often required, as soon as it has been established, to file a formal assurance document with the appropriate government agency. This requires the chairperson to follow specific steps – as dictated by the government agency – to coordinate his or her institution's administration with the government agency having authority to permit researchers to conduct trials with human participants, many of whom are considered 'vulnerable'. The authoritative body usually requires the newly established Research Ethics Committee to implement procedures and policies to ensure that research participants' privacy is protected, which often involves the creation of a system of computer codes as well as informational sessions for the potential participants.

Finally, there is at present a movement advocating the registration of any clinical trial that has been approved by a Research Ethics Committee (or its equivalent) and that conforms to existing regulations of the appropriate authority. The call has been both to investigators and sponsors of clinical trials that meet regulatory criteria. In some Member States, moreover, regulations mandate that clinical trials be openly registered (accessible to the public by Internet) if they are designed to evaluate the safety and efficacy of future treatments for life-threatening diseases.

2. Achieving credibility

Credibility is not granted or bestowed; it is earned. It is earned when the Committee persuades its constituency that the Committee's work is defensible, legally and rationally, and that it is rooted in traditions that have gained general acceptance. Committees must constantly tend to their credibility; which is to say that they must always put at the front of their minds the need to ensure that their work earns the respect of their constituencies. Committees cannot delegate their responsibility to others who, after all, have their own interests to protect; nor can they delude themselves that credibility lost can be easily regained. The signs of loss of credibility are, in their early stages, easy to miss or ignore. Committee members who take their credibility for granted may

not notice that they are politely ignored. After a while though, the unreturned messages, the failures to be consulted, the absence of invitations and the reduction in budget become impossible to overlook. At this point, nothing less than a change in Committee leadership and membership will be required; and internal procedures and external relations with constituencies and superiors will have to be rethought as well. All this is painful, difficult, and success is by no means certain. Recognition of this should encourage Committees to remain ever vigilant about protecting their credibility. If they lose their credibility, they cannot be effective, and if they lose their effectiveness they cannot appear credible. Furthermore, new chairpersons and members of Bioethics Committees will also experience the need to have outsiders respect and support the work they do. To achieve their goals, the Committee members soon come to appreciate the fact that they need clearly to define and disseminate their procedures and operations within their own settings and institutions and to formulate internal policies for pursuing their work effectively and efficiently, especially if they hope to be viewed by outsiders not only as competent, but also as credible and trustworthy.

Credibility problems are likely to be particularly serious for Health Care Ethics Committees and Research Ethics Committees. For they are closest to their constituencies and do not enjoy the prestige that hierarchical distance confers. Health Care Ethics Committees would be prudent to assess periodically whether they are respected among the staff, physicians and administrators who work within their health care organizations. Committees must be well organized, supported by their administrations with regular representation at meetings and an annual budget, and involved in current bioethical issues, as well as continually participating in self-education, or they will find that the members, or the chairperson, will become disillusioned. Those who do not fulfil the above criteria will soon absent themselves from the meetings and their credibility within the institution will dwindle.

Research Ethics Committees, to take another example, are not only charged with and accountable for protecting from serious physical and psychological harms, including harm to a person's dignity, those who participate in human research trials, but also mandated to approve research by carefully reviewing the scientific and regulatory aspects of research proposals as well as attending to the bioethical design of these protocols. To do any less runs the risk of failing to win and, in some cases, losing genuine credibility.

3. Health Care Ethics Committees responding to innovative biotechnologies designed to improve patient-centred care

People, wherever they live, expect to receive the best health care their country can offer. This care sometimes involves extraordinary technological innovations; but often this care is basic, if not minimal. In either case, though, patients do greet change with ambivalence, hopeful it will improve on what came before but fearful it might fail and not work as well. The point here is that how clinical medicine is practised depends in great measure on the public's attitude towards

technological advances and how it views and values therapeutic interventions. It is not a historical accident that the relatively few patients who have suffered severe trauma and are in a state of prolonged, deep unconsciousness (coma) have, following years of media attention, been the principal 'cause' of the establishment of Health Care Ethics Committees in Member States. Yet it is the everyday case, not the extraordinary and tragic case, that has come to occupy most of the Committees' time and attention. Health Care Ethics Committees play an important role in reassuring the public that an impartial, expert body is working to protect them from defective technological innovations.

4. Research Ethics Committees responding to innovative biotechnologies as outcomes of scientific and clinical research

Where do technological innovations come from? They may originate as ideas that emerge in moments of private contemplation. However, before they can be offered to the public, they must first be tested to establish their safety and efficacy. Initially, this testing ordinarily involves animals. If it proves successful, testing may be extended under controlled conditions to humans. The researchers' main focus, of course, is to use the participants to demonstrate the utility of the project. The idea of technological advance drives the entire enterprise.

At the same time, however, researchers must take care not to view the participants only as means to an end, but also as ends in themselves, that is as human beings entitled to be treated with dignity and respect. The research, therefore, should be devised and conducted so as to minimize risks to the participants, and the participants as individuals should understand the risks and benefits to themselves and to humanity before voluntarily agreeing to participate in the research.

In many countries, legislation and the threat of litigation, together with a public familiar with the concept of informed consent have meant that the interests of participants are generally well respected. In some countries, however, researchers may sometimes be tempted to take advantage of the indigent and the illiterate or to pretend that obtaining the consent of a leader obviates the need to obtain consent from individuals.

In all this, Research Ethics Committees play a vital role. In overseeing research, they must facilitate trials, which are indispensable to the progress of clinical medicine. However, they must also safeguard the interests of participants, especially when they are not fully capable of protecting themselves. Research Ethics Committees have acquired this vital duty not only to benefit the participants but also to benefit society at large. For if research were to fall into disrepute, it would be reduced and humanity would be denied many of its wondrous products. Many Member States have established Research Ethics Committees precisely because of the rapid advances in biomedical and behavioural medicine and biotechnology.

Research Ethics Committees are also expected to review research protocols in the field of public health and epidemiology. Therefore any protocol directed at screening populations for various indicators of latent or hidden (lanthanic) as well as so-called 'genetic' diseases must also be reviewed by a Research Ethics Committee.

The purpose of submitting a research proposal to a Research Ethics Committee is, in large measure, to prevent local abuse.

Part II

GENERAL AND SPECIFIC PROCEDURES AND POLICIES OF BIOETHICS COMMITTEES

1. General procedures and policies

The last thing Committees need is to create procedural complexity. Nothing could hinder their deliberations and negatively affect their recommendations more than establishing overly complicated procedures and policies that generate conflict and confusion among the members and interfere with the Committees' adopted purpose and functions.

Experience has shown that clarity can prevent misunderstanding and that potentially contentious procedural issues should be resolved before they become entangled in specific substantive disputes. Accordingly, the authoritative agencies that create Bioethics Committees should define the Committees' procedures and policies, if possible, before the Committees are constituted.

Each Committee should be assigned a mission statement which outlines its goals. Its jurisdiction should be separate and distinct from the jurisdiction of other Committees or institutional bodies.

Procedures for the recruitment of Committee members must be set out. Although recommendations for membership and indications about willingness to serve will naturally be sought informally, the actual appointment of the chairperson and members must follow regulated, transparent procedures. Criteria for membership should be clear. Thus, if a Committee is to represent various constituencies, these should be listed and the number of seats granted to each constituency made explicit. Typically, basic scientists, clinical researchers, physicians, nurses, pharmacists, bioethicists, clergy, health lawyers, behavioural scientists, social workers, patient advocates, administrators, laypersons and public officials are among the relevant categories represented.

It must also be determined whether the members serve for as long as required by those who appointed them or, instead, for fixed terms. If the terms are not fixed, then it must be

determined whether the terms should be staggered or coterminous and how long they should be. Related to this is the matter of removal. Should the appointing authority be permitted to remove a member only for cause (malfeasance, incompetence, incapacity) or should its power be entirely discretionary, which would include policy, partisan, and personal differences?

Arguments can be made for either choice, but it is usually the larger considerations that influence the decision. One such consideration is the extent to which the Committees should be independent of the granting official. The official, either elected or responsible to an elected official, may believe that Committees should carry out his or her policies. This would imply the official holds broad powers over the membership. Committee members, on the other hand, may feel that, like courts, they should be insulated from popular pressures. This would imply only narrow powers over the membership. A second consideration is stability. The Committees and society in coming to an accommodation with rapidly changing biotechnologies, must allow people time to adjust without being confused and disoriented by the unfamiliar and uncertain. If change promises benefits, it is not helpful if Committees slow the pace of change thereby delaying the benefits. The rate of turnover in Committee membership may help to determine how willing the body is to accept or reject the new. A third consideration is the interpretation given to a Committee's mandate to be representative. If 'representative' is taken to mean resemblance, the Committee should represent society in roughly the way a sample of people represents the population and emphasis would be placed on having a variety of interests represented. If, however, 'representative' is thought of as agency, the Committee should represent society in roughly the way a lawyer represents a client and emphasis would then be placed on expertise.

It must also be determined how a Committee's agenda is to be set. Is the Committee assigned problems by other officials? Can it construct its own agenda? Is it dependent, like courts, on disputants who bring it issues? Can it pick and choose among these issues, selecting the most salient ones or those it considers ripe for decision? Or must it respond to whatever is asked of it? These considerations may be decisive in determining the nature and importance of the Committee's work.

How the Committee deliberates must also be decided. In the nature of things, many of its discussions will occur informally and hidden from view. Should it eventually be required to hold open meetings, to publish its decisions or to provide written justifications for these decisions? The Committee's business is the public's business, and the public (or its representatives, officials, or the media) may demand openness as a means to accountability. Decision-making, however, calls for candour, bargaining and compromise – qualities that tend to fade with publicity.

Even if a Committee's meetings are private, however, the question remains as to how they should be conducted. One path would be to follow a particular set of rules of procedure such as those of UNESCO's International Bioethics Committee (see Appendix I). These rules

of procedure should be set out clearly, before the game is played so to speak, and they should be familiar to all the participants. Particular issues should be addressed in an orderly fashion and votes would reveal exactly the extent of support and opposition on specific issues. An alternative path would be to proceed informally and seek consensus. This usually magnifies the power of the Committee's chairperson – opposition that is intimidated into silence cannot vote no – though consensus is typically defended as friendlier and easier to follow than a set of formal rules.

Whatever path is taken, records must be kept in a secure fashion. The question as to who has access to these records and under what circumstances is important. Firstly, this may affect the Committee's deliberations. Fear of exposure may affect discussion and voting. A member willing to take an unpopular position behind closed doors may be dissuaded by the fear that his or her position may shortly be made public. Secondly, there are the twin issues of confidentiality of information and privacy of persons involved. Morally and legally, there are obligations to respect confidentiality and privacy.

Yet the demand for secrecy also raises the old question of who guards the guardians. Secrecy may be used to cover up abuse. Though sunlight is a great disinfectant, it may not penetrate layers of privacy and confidentiality claims, and in the darkness incompetence and even criminality may thrive.

More fundamentally, secrecy is an obstacle to accountability. Committees are not free-floating entities, answerable only to themselves. They exist in a complex institutional context, and with their power to do good or ill, must be held accountable for their actions. But to the extent that information as to these actions is not provided, efforts to hold Committees accountable may well be frustrated.

At the same time, of course, just as Committees may on occasion demand secrecy to hide abuse, so may outsiders demand openness to further their own careers, embarrass members, or appeal to popular prejudices or fears.

In this, the role of the media is apt to be decisive. For apart from narrow sections of the biomedical community, the public may be entirely unaware of the Committees' work, probably even of the Committees' existence. It is the media, usually highlighting spectacular successes and failures, who bring the Committees to public attention. Accordingly, Committees are well advised to cultivate key media operatives both to help generate long-term public support and to minimize the predatory impulse in times of crisis. A roused public may affect a Committee's authority, budget, or membership, so a Committee neglects public relations at its peril.

There are a number of questions that chairpersons and members must answer with respect to establishing sound procedures:

1. If those in authority have not selected and appointed all the members of the Bioethics

Committee prior to its establishment, what procedure will be used for filling the remaining positions?

2. Does the Committee include an adequate number of basic scientists, physicians, nurses, allied health professionals, clinical pharmacists, bioethicists/philosophers, clergy, social workers or patient advocates, attorneys, administrators, public officials, lay persons or other resource persons? Is a particular expert needed?

3. Has the tenure of each member been determined? Are the terms of appointment permanent or staggered?

4. Has the Bioethics Committee determined its mandate – its purpose, functions and policies? This will definitely depend on the form of the Committee.

5. Concerning financial support, has the Bioethics Committee determined the provisions that must be made for it to carry out its mandate? Clearly, an annual budget should be formulated; it should reflect, in detail, income (if any) and expenses.

6. Has the Bioethics Committee established a policy which indicates who will be authorized to bring to it bioethical problems and dilemmas, raise bioethical issues and address conflicts and dilemmas? At times, the Bioethics Committee must also determine whether it is mandated to deliberate certain bioethical problems and dilemmas, that is, whether a particular type of clinical case or research protocol should be brought before the Committee.

7. Has the Bioethics Committee determined whether its meetings will be open to the public? Never? Always? Periodically? It should be clear who formulated this policy and the policy should be publicly announced.

8. Has the Bioethics Committee established standard procedures and policies for retaining custody of its confidential records and documentation? It should also determine who would be authorized to access the Committee's files. What will be retained in these files and for how long? What may be discarded and when?

9. With respect to written and oral documentation, has the Bioethics Committee established procedures and policies to ensure both the confidentiality of information and the privacy of those persons with whom the Committee interacts?

10. Will the functions of one form of Bioethics Committee be extended to include the mandate of another Bioethics Committee? Each Committee should determine, if it is asked to accept what is clearly the mandate of another form of Bioethics Committee, whether it can or will comply with such a request.

11. Has the Bioethics Committee determined how the public and the media will be informed of specific decisions, which require consensus regarding the internal policies the Committee adopts?

12. Has the Bioethics Committee determined how it will continue to educate itself in bioethics? A description of such educational programmes should indicate how future members would be educated in bioethics before they actually serve as chairpersons and members.

The above twelve points to be considered when establishing Bioethics Committees are summarized in the box below.

ESTABLISHING PROCEDURES AND POLICIES FOR BIOETHICS COMMITTEES

1. Appoint the chairperson and all the members
2. Appoint members with diverse specialties and expertise
3. Determine the tenure and terms of all appointments
4. Review the Committee's form, i.e. its mandate, purpose, and functions
5. Establish an annual budget
6. Create a policy that identifies who may access the Committee, and whether certain issues must be brought before it for review
7. Establish a policy regarding the presence and participation of non-members, including the lay public
8. Determine the procedures for documenting, retaining custody of, and accessing the Committee's confidential files and records
9. Establish mechanisms to protect persons' privacy and to maintain and secure their confidential information
10. Review periodically the Committee's mandate and determine if it should be extended to include additional functions
11. Determine how the media and the public will be informed of the Committee's activities: advising, recommending or decision-making
12. Establish a bioethics self-education programme for present and future chairpersons and members

1.1. Chairpersons' and Members' Roles

Chairpersons are expected to clarify their mandates, carry out their duties and lead the Committees' meetings. If Committees' mandates are too broad, however, it may prove difficult for them to proffer advice or recommendations that are practical. This alone requires that the chairperson form a plan: prepare a coherent agenda, discuss key items with the members beforehand, conduct the meetings impartially and expeditiously and follow up after the meetings adjourn. Chairpersons may be very influential in setting agendas, establishing priorities and distributing workloads, particularly when assigning members presentations or requiring written papers on specific topics the Committee is expected to deliberate. Many chairpersons choose instead to solicit items from the members for the broader, detailed agenda, a process which may require numerous meetings preceded by numerous informal exchanges. This process may serve to help the chairperson identify any serious objections from the membership, and therefore should be undertaken at least a week before a meeting convenes.

Committee members should plan to attend all meetings and plan their normal, monthly workloads accordingly; even if they are members of the Committee's subcommittees, the same rule applies. Like the chairperson, each member should, having received the meeting's agenda, prepare for that meeting and understand the nature of the items on the agenda. This will enable each member to participate actively and perhaps to provide crucial information in order to achieve the Committee's goals. At each meeting, every member should be in a position to offer suggestions as the chairperson moves through the agenda.

Committee meetings are, after all, interactions among individuals, each with his or her own hopes and fears, goals and obstacles, allies and adversaries, temperaments and habits; at times, such interactions may be with invited guests. Meetings reflect these often hidden dimensions and sophisticated members look for clues on the dynamics that accompany and sometimes displace the Committee's formal business.

For a number of years, social psychologists who have studied group dynamics – not just 'group think' – have known that a Committee's deliberations, especially its outcomes, are generally superior to those of any individual so-called 'average' member and are usually at least equal to those of the best members, though groups do at times produce inadequate or barely adequate solutions for the sake of compromise; they sometimes even choose to follow a very risky course (perhaps because each member believes he or she bears no personal responsibility). In addition, groups often, but not always, provide more helpful advice and more informed recommendations and decisions than individuals. Bioethics Committees must be careful, however, when they attempt to take advantage of these general findings, and work to improve their Committees' deliberations, advice, recommendations and, when necessary, decisions.

Finally, as experienced chairpersons have learned first-hand, problems, unworkable procedures and unhelpful policies usually receive the most attention from members. It is important, therefore, for chairpersons, to inform the members periodically that their work is appreciated. This may encourage the members and subcommittees to undertake additional obligations voluntarily.

1.2. Recruiting Members

Once the role of the Committee has been determined, it must be filled in order to function. The quality of membership will obviously be crucial in determining its success. Well chosen members can often make even badly designed institutions work; poorly chosen members can doom even the best designed structure. Bioethics Committees face a common problem: many unqualified persons may wish to serve, and many qualified persons may not wish to serve. How does one recruit the qualified, not the unqualified?

The most obvious approach would be for chairpersons, Committee members and

institutional officials to take the lead and encourage qualified persons to serve. Informal meetings and invitations to seminars and conferences are among the many techniques that might be utilized. This approach has the advantage of giving the initiative to those with experience and knowledge. It also seeks to make practical use of the networking in which everyone would be involved. The most obvious problem is that this approach would impede change – recruiters would naturally seek out persons who agreed with them – and the weeding out of abuse – new members might feel a debt of gratitude to older members.

It is fortunate, then, that this process has always been supplemented by a second process of interested constituencies putting forth candidates of their own. Both processes suffer from the same defects but the two approaches will usually check and balance each other.

All chairpersons, in any case, understand that they must make Committee membership appear as attractive as possible, emphasizing its prestige, importance and perquisites, and understating its burdens (time, energy, risk of alienating valuable persons). Appeals to altruism and a responsibility to the public should also be made, and it may be useful explicitly to renounce the role of the 'ethics police'.

There are, however, also forces at work to discourage people from volunteering to serve on Bioethics Committees:

1. Some stakeholders may simply be hostile or indifferent to the existence of these Committees. Internal in-service and continuing educational programmes may help to overcome this attitude.

2. Experts may assume, usually mistakenly, that there are simply too few bioethical issues to warrant continuing agendas for these Committees. Committees can publish and disseminate their agendas to challenge this assumption.

3. Professionals and scientists may be so occupied in carrying out their formal duties that they simply do not believe they have the time to devote to Committee work. Chairpersons, however, may contact administrators and others to seek their support in restructuring the schedules of busy professionals to allow them time to serve on a Bioethics Committee.

4. People may want to avoid the controversies they believe the Committees invite.

5. Many experts, professionals and staff simply do not know what the Committees'purpose and functions are. Administrators may support chairpersons by disseminating statements explaining the purpose and functions of the Committees within their institutions. Establishing a policy to invite periodically a few non-members to attend each Committee meeting may clarify the Committee's purpose and functions and even serve as a way to gain non-members' support.

One issue is whether Bioethics Committees should include ex officio members. An advantage of having ex officio members is that it would ensure representation from certain

interest groups whose participation may be regarded as helpful. For example, a Policy-Making and/or Advisory Committee might be required to include a representative from the ministry of health, and a Research Ethics Committee might be required to include a biostatistician from its institution. However, ex officio members do not always serve with enthusiasm and other members of the Committees may regard ex officio members as having unearned influence.

Adding ex officio members to Bioethics Committees should be arranged with care in order to avoid giving even the appearance that the Committees are attempting to bypass their own administrations' authority. Experience has shown that representation of non-members on Bioethics Committees proves far more effective than merely disseminating periodic reports. Chairpersons of Bioethics Committees may be able to establish useful relationships with experts and officials; this could lead to more fruitful Committee discussions when they deliberate on difficult cases (whether past, present or hypothetical), newly submitted human research proposals, and proposed science and health policy initiatives.

1.3. Preparing for Meetings

Chairpersons who hope to conduct worthwhile meetings need to do more than acquire information for creating agendas. In the early stages of a Committee's existence, it should establish procedures about how often it will meet and whether alternates or substitutes will attend when regular members are unable to do so. Will the Committee convene only when a case or protocol emerges that calls for review? Will it at times be required to provide mandatory review? Is a quorum necessary? If so, what are the criteria? A quorum is the minimum number of members – including the chairperson – required to attend (and particularly to vote at) the Committees' meetings. Some meetings may actually require the presence of at least one member with scientific competence or training in a particular clinical sub-speciality.

Who can request a review, for example, of an in-patient's case or a research protocol? Who decides whether the case or protocol is appropriate for review? If judged inappropriate for review by the chairperson alone, has she or he communicated this fact to all the members? In the case of Bioethics Committees, the answers to these questions may come by way of mandates from highly placed elected and appointed government officials, health care institutions' administrators or requests from a variety of health professionals.

Requests in themselves, however, are not sufficient to warrant a Committee's attention and deliberation. There should be a problem, or set of problems for which there is a need to provide, through careful deliberations, relief or resolution.

Preparing for meetings requires an open door policy on the part of chairpersons as well as Committee members. Not all Committee meetings are expected to resolve bioethical dilemmas; Committees are often called upon to disseminate important facts, which may include decisions made elsewhere – within and without the Committees' particular settings –

or to discuss anticipated problems that have not yet been brought to the Committees' attention but that the chairpersons believe may become agenda items in the not-too-distant future.

1.4. Following Agendas

Since an agenda is a list of topics to be addressed at a meeting, it may be somewhat open-ended. There is usually another item called 'Any other business' that members can use to raise an issue which concerns them and which serves as a guide to the business to be conducted.

Sometimes agendas are too ambitious. Perhaps, for example, an item provoked more discussion than had been anticipated and the meeting ends before all items have been covered. In that case, the items not covered are normally carried over to the next meeting. The chairperson could also ask the members, before or at each meeting, if an agenda item should be eliminated if it appears to be of no interest to the members. Detailed timelines can also be established for the production of the Committee's reports. Finally, before the meeting, members can be asked if any of them intend to divert the discussion to personal, more immediate concerns that are not on the agenda.

1.5. Recording Minutes of Meetings

Minutes are a record of what transpired at a meeting. Minutes may be detailed, providing abstracts of discussions, or they can be limited, simply noting action taken. As minutes may be used to record precedents or rationales for use or to inform authorities or the general public, the kind of minutes kept may have important practical consequences.

Sometimes Committees employ professional transcription services. When they do so it may be best to restrict the service to audio and not video recording. The important thing is to produce a 'clean' document three or four days after the meeting has adjourned, since the initial transcriptions are usually quite 'rough'. Once available in clean form (the task assigned to the staff), the transcriptions can be forwarded to all the members for review. Within a week, the final version of the Committee's meeting could be available and possibly placed on the Committee's website. Some Committees have adopted a policy in which the standard task is to clean up the initial text for 'transcription error' but not for 'speaker error'. This procedure has the advantage of dissuading members from assuming that they can always revise and extend their remarks at a later time.

The minutes are typically retained by the Committee's secretary, who is usually appointed by the chairperson. She or he compiles the minutes and circulates them to the membership at least one week prior to the next meeting so that they can be reviewed for accuracy and completeness. After approving the meeting's agenda, the members are asked to approve the minutes of the previous meeting, after which they become part of the Committee's official records.

Some members have expressed concern that minutes may be used against them in legal proceedings to help establish civil or criminal liability. The evidence to date indicates, however, that neither Bioethics Committees as a whole, nor their individual members, will ever face civil or criminal liability for advice or recommendations made in good faith. Indeed, judges tend to appreciate the fact that official records have been retained rather than ignored or discarded. In fact, in some Member States Bioethics Committees and their members may be provided, by their institutions or other bodies, with immunity from all civil or criminal liability.

1.6. Establishing Subcommittees

It is frequently no longer feasible for the large number of established Bioethics Committees – each convening as a full Committee sometimes more than once a month – to achieve their purposes, carry out their functions and realize their specific objectives. In many cases their workloads have become a serious burden, since virtually all Committee members serve on these Committees in addition to their regular duties.

One solution is the establishment of subcommittees within an existing Bioethics Committee to achieve a division of labour based on expertise and interest. Such subcommittees, usually small and nimble, can also act with greater speed and effectiveness than the often large and unwieldy Committee. Institutions and their administrations, as well as Committee chairpersons, often choose to rely on subcommittees (which can be created by adding a few more members to each Committee) to convene a number of times between meetings of the full membership. Occasionally, particularly at the national level of government at which Policy-Making and/or Advisory Committees operate, the establishment of subcommittees, though perhaps useful, are not organized. A Member State may have adopted 'open meeting' requirements, and this alone would make it cumbersome to transact Committee business through a number of formal subcommittees.

Nonetheless, since self-education is of major importance to and a continuous activity of Bioethics Committees, virtually every Bioethics Committee eventually needs to form a subcommittee to organize and carry out self-education, not only for the subcommittee's present members, but also future members. In addition, the subcommittee may be given the task of organizing programmes to educate the public on basic bioethical concepts and issues, particularly for people residing in each institution's local community.

Some Bioethics Committees have established subcommittees whose tasks are:

1. to establish policies for selecting chairpersons and members;

2. to prepare and review informed consent forms for patients and participants in clinical research trials;

3. to address significant bioethical issues that pertain to critically ill patients;

4. to review bioethical issues for multi-centre clinical trials, e.g. between the host State and other Member States;

5. to establish plans for the financial support of the Committee's activities;
6. to promote bioethics education for institutional personnel and local citizens; and
7. to produce various bioethics publications.

1.7. Follow-up and Interim Activities

After a meeting adjourns, follow-up may be necessary to ensure that Committee decisions are implemented. The chairperson, perhaps in concert with interested Committee members, is expected to take the lead. Determined, forceful follow-up not only enhances the credibility and self-esteem of the Committee, but also provides tangible evidence of its effectiveness. A pattern of follow-up also encourages vigorous implementation by raising the likelihood that passivity will be criticized.

Follow-up, however, is often time-consuming and tedious, directing efforts towards administrative detail and not intellectual challenge. Chairpersons, therefore, often undertake this essential task half-heartedly. Trusted staff, acting in the chairperson's name, are often more helpful.

In addition to requiring that minutes of all meetings be taken and distributed in advance of the next meeting, chairpersons might also establish routine procedures for distributing memoranda that serve to remind the members of what they previously agreed to accomplish. Similar procedures should be adopted and followed by subcommittees. Such memoranda, usually sent to all members, can serve to remind and perhaps even motivate those members who have not yet completed their tasks.

1.8. Committee Networks

Particularly at the local and regional levels of government, Bioethics Committees may be able to combine their resources, however limited, and together address systemic problems as well as formulate and adopt common work procedures and policies. All too often, similar Bioethics Committees fail to take the opportunity to share their experiences with other providers of care (in the case of Health Care Ethics Committees) and among clinical researchers (who serve on Research Ethics Committees). The mutual sharing of experiences among different health care providers who practise in different environments can create transdisciplinary learning, which would improve the way bioethical issues are addressed not only in terms of the individual patient but also in terms of the system of care. The sharing process may also serve to influence the formation and development of new approaches to local and regional health policies. In short, collaboration among representatives from different settings, disciplines and institutions may help create a broader understanding of the common bioethical issues that emerge from the various health care settings within the network.

Once Bioethics Committees agree to form a regional or local network, they may establish a flexible agenda for convening a forum and select specific topics by calling upon all the

participants to provide suggestions. In the Veneto region of Italy, for example, authorities have established a regional Bioethics Committee and beneath it, a system of Health Care Ethics Committees in the major hospitals as well as Research Ethics Committees in research centres and university hospitals. These Committees at their various levels try to coordinate their activities. Since 1988 Italy has had a Bioethics Committee at national level.

Committee networking may be facilitated through conferences. In order to make these conferences productive, the following specific steps may be helpful:

1. Small groups of participants, perhaps joined by a common institutional or organizational affiliation or geographic setting, may convene to discuss their particular interests.

2. Small groups may also rank in order of significance 5 or 6 interests based in part on the type of institution to which they are affiliated (hospital, regional health care or referral clinic, long-term care institution).

3. Small groups may decide which major topic or interest area will be discussed at a special session.

4. At a plenary session, individuals from each group may report on the discussion.

5. At the final session, a summary of the work of all groups may be distilled and specific, well-focused tasks important to the group outlined.

These forums may not only contribute to resolving specific problems, but may also enhance inter-group knowledge and understanding as members of each group interact with and learn from members of other groups. One result of this process is that local and regional participants may well come to appreciate the types of problems that others encounter, often noting how similar the problems are notwithstanding the difference between their institutions as well as their local and regional settings.

The rethinking that ensues may constitute a resource that members call on in the future to gather information and ideas. To facilitate such rethinking, forums should not be burdened with too many formal obligations. Ample time for informal discussions and question-and-answer sessions should be provided. It cannot be stressed enough that insufficient time is the prevalent failing of most conferences and Committee meetings. Participants often, in retrospect, regret having tolerated such a frustrating and unrewarding programme in silence. This problem can be addressed by drawing the attention of the organizers of future conferences to the need for a new internal policy to rectify this serious procedural problem.

These specific steps are not ends in themselves, of course, since Committee networks' procedures alone cannot replace the sharing of experiences; these can come only from a well-organized conference or forum.

2. Specific procedures and policies

2.1. Policy-Making and/or Advisory Committees

Responding to governments' agendas

Policy-Making and/or Advisory Committees do not simply carry out the mandate given by the head of government. They must also be prepared, at virtually any time, to respond to requests from government agencies for advice or assistance in making new science policy. Individuals outside government usually do not have access to these Committees, though at times lobbyists can find ways to contact the chairperson or a member of a Committee in order to suggest that the Committee consider a particular topic when the Committee convenes.

Policy-Making and/or Advisory Committees in a number of Member States have, in accordance with their specific mandates, adopted procedures to advise the head of government and other government officials, to effect the promotion of health policy at national level (see Appendix II.2).

The staff and its working procedures

The members of Policy-Making and/or Advisory Committees usually reside long distances from the venue of their meetings. This is not the case, however, for Research Ethics Committee or Health Care Ethics Committee members, who usually convene in the local or perhaps regional area, though some Member States' Policy-Making and/or Advisory Committees are actually Research Ethics Committees, and their members must also travel to convene at national level. On the other hand, full-time staff members of Policy-Making and/or Advisory Committees must reside near the venue of the Committees' meetings, since they are continuously involved in the Committees' deliberations, especially meetings resulting in rather lengthy transcripts requiring follow-up. Staff members must be local since they are enjoined to synthesize, publish and assist in disseminating the work of the Committee members – a monumental task at times.

An added problem is that there really is no single way for staff to prepare the statements or reports of a Policy-Making and/or Advisory Bioethics Committee or Council at national level, although it falls to the staff:

1. to review all the 'rough' transcripts of each meeting;
2. to summarize accurately the diversity of views of the members;
3. to integrate the previously-assigned working papers; and
4. to perhaps even transcribe the 'clean', synthesized document and enter it on the Committee's existing website so it becomes accessible on the Internet.

Policy-Making and/or Advisory Committees should not ignore the need to develop internal guidelines and operating policies. These are needed for it to accomplish effectively its advisory role. These operating procedures and guidelines should contain definitions pertinent to the topic or bioethical problem, criteria for the statements and reports they are preparing, a description

of the process for soliciting the participation of consultants, when needed, and a detailed job description of the members of its full-time staff.

Since Committees are expected to prepare reports for the government officials to whom they are responsible, they need to convene in an atmosphere of trust and mutual respect. When members convene to discuss a particular topic or problem in bioethics, they must be accorded an opportunity to be heard and to exchange views.

Producing reports and Member States' national archives

One of the most difficult tasks for a Committee is to produce lucid, comprehensive and comprehensible advisory reports that it can forward to the head of government's staff members and perhaps to other elected or appointed government officials, including ministers. These statements should also be educational. For although they may not affect policy in the short run, they may have a significant impact later on. Thus, Policy-Making and/or Advisory Committees are expected to develop detailed, internal guidelines, as though their advisory reports or statements would one day be approved and lead to new policies. At the national level of government, if not at lower levels, all documentation with respect to the work of a Bioethics Committee should be retained in the Member States' national archives. In time, these documents may prove of great value for historians, policy makers and others, as future generations hope to learn from the past.

In a number of Member States the operating procedures of Committees may represent a formidable task, since numerous health policies may be under discussion at any one time by those whom the members advise and to whom they report. If these reports, in the end, influence the formulation and adoption of national policies that improve the public's well-being, all the better.

2.2. Health-Professional Association Bioethics Committees

Responding to health professionals' bioethical concerns

Chairpersons and members of a government's Policy-Making and/or Advisory Bioethics Committee may have adequate authority to influence Health-Professional Associations' Bioethics Committees. A government Committee at national level may, for example, contact a Member State's medical, nursing or pharmacy associations since they may be affected by a proposed or new policy. As an interested party, such a government Committee would naturally believe it was entitled to try to influence the formulation and implementation of that policy, either out of self-interest or a conviction that with their knowledge and experience they could improve it. Often, a given proposal may interest several Committees. If they share common interests, they may coordinate their responses; if their interests diverge, their responses will reflect this, and the resulting conflict may negate all their efforts.

Health-Professional Association Bioethics Committees are not large. Usually, they have about ten members, virtually all of whom are educated to practise the same health profession, although a Committee may include a graduate medical, nursing or pharmacy resident who has not yet begun to practise. A lay person may also be invited to join the Committee, either by the leaders of the association or by a more formal process of nomination and vote. The term of office of Committee members may be as long as seven years or as short as two or three. Members appointed for long terms are usually informed when they join that their term of office is non-renewable.

In short, owing to the small size of the Committee, personal relationships among these Bioethics Committee members are often decisive in shaping responses.

Internal policies under review or development

Drafts of reports or statements of Bioethics Committees pertinent to newly proposed health policies are usually transmitted to the relevant standing Committees of the association. In addition, these drafts may be forwarded to other Bioethics Committees and to other interested parties for comments. This procedure may help bring about consensus among the members of these Committees when they propose policies for ratification at meetings of their General Assemblies, thus avoiding time-consuming debate over minor matters on these occasions.

An association may appoint a working group or task force to oversee the review process. The secretariat of the Committee is usually responsible for organizing and collating its comments into a single document or statement, which will be reviewed once again by the entire Bioethics Committee. At this point, the Committee may recommend to the leadership of the association that the policy it has proposed be adopted. The leadership, in turn, may require further revision or inform the Bioethics Committee that it chose not to approve the Committee's report. However, when a report is approved by the leadership of an association – which has the final authority within the association – the report becomes association policy. This same procedure may well be followed by a Health-Professional Association Committee when asked to amend its association's existing external policy statements.

Finally, Committees would be well advised to call for a review of their internal policies and guidelines at regular intervals of no longer than five to seven years. These internal working procedures and operating policies may (1) be reaffirmed with no or only minor changes; (2) undergo major revisions; or (3) be replaced or eliminated. A periodic review will ensure that internal policies and guidelines do not outlive their usefulness. In any case, the leadership of an association may require that it formally receive these proposed procedural changes from its Bioethics Committee so it may review them before giving its final approval to the chairperson.

Reporting to the association's Assembly or House of Delegates

Health-Professional Association Bioethics Committees are only one among many kinds of Committee in health-professional associations – groups of physicians, nurses, pharmacists, and so forth. All Committees of professional associations are expected to follow the same working procedures, including reporting the results of their deliberations to the organization's General Assembly on an annual or biannual basis.

The General Assembly, sometimes called the House of Delegates, is composed of a large number of representatives of the overall membership. Health-professional associations are usually governed by procedural rules established by the association's by-laws, which are ultimately established by the House of Delegates or General Assembly. One of its subcommittees, a Reference Committee whose members are usually selected by the association's leadership, may be charged with the responsibility of accepting the Bioethics Committee's annual report and choose to convene with some of the Committee members before or during the annual meeting of the Assembly in order to discuss the report and its recommendations. The Reference Committee may accept, reject or require modification of the Bioethics Committee's report.

Once accepted, which may take some months, the report may move forward to the association's leadership and eventually to the General Assembly for ratification. The Reference Committee may be composed of five to ten members. The Reference Committee, as is the case for all Committees, usually has the financial support of the association's general revenues that are distributed by the association's leadership.

The staff of a Health-Professional Association Bioethics Committee, whose duties are quite similar to the staff members of Policy-Making and/or Advisory Committees at the national level of government, often comprise no more than five or six members. Informal surveys reveal that this is not usually an adequate number of people to complete the heavy workload required by the Health-Professional Association Bioethics Committee.

Ethics standards: professional codes of conduct, enforceability, and sanctioning members

A Health-Professional Association Bioethics Committee is only one of several Committees, and is not usually involved in accepting or rejecting applications for membership in the association. Although members of the Committee are usually appointed by a Committee of the association's House of Delegates, this Bioethics Committee is usually quite independent and only nominally accountable to the House of Delegates. The internal policy of some associations is for members of its Bioethics Committee, once appointed or elected, to serve for five or seven years. These long terms have the advantages of promoting continuity and, by extending members' self-education in bioethics, help guarantee expertise. Some believe that Committee members should be required to resign from all other positions within the association, especially if they are serving as

delegates to the General Assembly, to avoid giving even the appearance of a conflict of interests within the association at large.

Health-Professional Association Bioethics Committee members may be asked to pledge to uphold the ethical standards (or principles) of the association. These standards are typically found in the association's ethical code.

For example, consider the following International Code of Medical Ethics promulgated by the World Medical Association:

DUTIES OF PHYSICIANS IN GENERAL

A physician shall always maintain the highest standards of professional conduct.

A physician shall not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients.

A physician shall in all types of medical practice, be dedicated to providing competent medical service in full technical and moral independence, with compassion and respect for human dignity.

A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud and deception.

The following practices are deemed to be unethical conduct:

A. Self advertising by physicians, unless permitted by the laws of the country and the Code of Ethics of the National Medical Association.

B. Paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring a patient to any source.

A physician shall respect the rights of patients, of colleagues, and of other health professionals and shall safeguard patient confidences.

A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

A physician shall use great caution in divulging discoveries or new techniques or treatments through non-professional channels.

A physician shall certify only that which he has personally verified.

DUTIES OF PHYSICIANS TO THE SICK

A physician shall always bear in mind the obligation of preserving human life.

A physician shall owe his patients complete loyalty and all the resources of his science.

Whenever an examination or treatment is beyond the physician's capacity he should summon another physician who has the necessary ability.

A physician shall preserve absolute confidentiality on all he knows about his patient even after the patient has died.

A physician shall give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

DUTIES OF PHYSICIANS TO EACH OTHER

A physician shall behave towards his colleagues as he would have them behave towards him.

A physician shall not entice patients from his colleagues.

A physician shall observe the principles of the "Declaration of Geneva" approved by the World Medical Association.

In addition, standards of ethical conduct may cover the following: professionalism, responsibilities to funding agencies and the public, and misconduct in preparing and publishing the results of basic research. Misconduct, however, goes beyond fabrication, falsification, and plagiarism, and includes the failure to honour obligations to vulnerable participants in clinical trials that require comprehending the complexities, for example, of statistical models in psychological and sociological research. While a research trial is in progress, for example, the ethical obligations of statisticians include informing principal investigators in a timely fashion that certain ongoing trials should be stopped owing to new and documented evidence of unacceptable risks of harm to the health and life of the participants.

These scientific associations and societies do not usually have the authority to rule on allegations of scientific misconduct or to arbitrate ethical matters. They do not usually accept the task of reviewing, adjudicating or imposing discipline for scientists' misconduct, which usually becomes the task of the researchers' institutions or, if deemed necessary owing to government funding of the research, government agencies. However, some scientific associations do have formal procedures for dealing with allegations of scientists' misconduct. In any event, virtually all of these associations provide guidance to their members, upon request, on ethics-related issues of concern to the membership.

However, codes of conduct are not always adequate when one seeks specifically to guide professional conduct, to resolve ethical dilemmas and to provide sound advice or recommendations. Such codes are generally aspirational and, in addressing the association's membership, take little account of the interests of other parties.

Pledges to uphold a set of ethical principles are not, however, enforceable. A Bioethics Committee may play a significant role should occasions arise where a member of the association is in jeopardy of being dismissed, especially if the Committee is mandated to address not only bioethical issues but quasi-legal issues as well. The Bioethics Committee may, at times, be asked by a licensing board to evaluate allegations that a member of the association has acted unprofessionally and should therefore be investigated for possible professional misconduct. However, Committees are usually not investigative bodies. Most Committees rely on information from other entities, primarily licensing boards, to identify members whose professional conduct may not be in accordance with the health profession's code of conduct. Bioethics Committees tend to view charges of misconduct in terms of definitions provided by the profession's licensing board. If the charge is proved, the Committee may have the authority to exclude the member from the association and 'request' that he or she resign. Ultimately, the Committee may impose various sanctions against any of the association's members, ranging from denial or revocation of membership to probation, mere monitoring, or

such lesser sanctions as censure, reprimand or admonishment. Sanctions usually result from lengthy procedures that conform to due process, including the right of the professional charged to be granted a hearing before the appropriate body of the association.

Finally, Bioethics Committees have also been known to submit advice, whether invited by a court or not, by way of filing an amicus curiae brief in response to a patient's legal charge of professional misconduct, especially when the case has significant implications for the health-professional organization or its members.

Public access and publications

Health-Professional Association Bioethics Committees often publish newsletters as well as journals for their health-professional members. Typically, subscriptions are included in the members' annual dues. The newsletters, written to inform the membership, feature informal articles on the organization and its activities. Increasingly, newsletters have been supplemented by websites which serve the same function, but are more easily updated. Journals, on the other hand, are peer reviewed scholarly publications. Newsletters and journals may focus on bioethical issues from time to time, but Committees will usually have to look elsewhere for knowledge and information – most likely to specialized journals and books, to invited experts, or to conferences on the subject.

Although it is difficult for the public to access Policy-Making and/or Advisory Committees at the national level of government, this is not the case with Health-Professional Association Bioethics Committees. Throughout any given year, these Committees may well receive hundreds of inquiries – letters, emails, telephone calls – from persons inquiring about, for example, the association's position with respect to a patient's case that has been covered extensively by the media: 'Why this decision?' 'What's actually being done?' 'Here's what I believe….'. Bioethics Committees may regard these inquiries as distractions or nuisances, but these are opportunities to cultivate favourable public relations, and so they should be treated accordingly.

2.3. Health Care Ethics Committees

Procedures and policies for accessing the Committee

First, Health Care Ethics Committees may differ with respect to whom they are accountable. Once established, they may be accountable to the health care institutions' medical staff, administrative staff, a combined Committee of medical and administrative staff, or to other bodies, such as divisions of pastoral care, departments of social work, nursing Committees, or even the chief executive officers of the institutions.

Second, Health Care Ethics Committees may have widely varying policies regarding who may bring a bioethical problem to their attention. The two extreme policies are: (1) that any stakeholder, including a patient's family members, and interested non-

health professionals may contact the chairperson or any member of the Committee; and (2) that only the institution's physicians who care for in-patients may access the Committee.

Policy (1) presumes that newly admitted patients are informed of the existence of the Bioethics Committee. To ensure this information is conveyed, patients and their families must be provided with brochures, handbooks or newsletters; or the division of pastoral care or patient advocates or representatives may be required to inform patients and their families of the existence of the Committee. Policy (2), permitting only medical staff to access the Committee, would require simply that the chief of the medical staff announce the Committee's presence within the institution. This policy insulates the medical staff from controversies because it screens out other stakeholders, including non-medical staff, patients, families, and others residing in the local community, who may urgently need to discuss general but pressing bioethical issues.

Today, considerable time and energy is spent informing newly admitted patients, their families and others of the existence of the Bioethics Committee, and encouraging them to access the Committee. New employees of a health care institution are also informed of the Committee's existence. The purpose and functions of the Committee are usually discussed in detail during periodic staff meetings. In this way, the Committee becomes visible throughout the institution's communication network, which may extend to the local community. Carrying out the policy of open access is a continuous process, however, and each Health Care Ethics Committee is free to adopt and follow procedures that best suit its institution and staff. This approach usually serves patients' and their families' interests as well.

Procedures and policies for the bioethical review of patients' cases

Bioethics Committees may be eager to address the urgent, complex, and fascinating issues with which they are confronted. The fact that the members are nearly always occupied with multiple obligations only magnifies their impatience. But this impulse should be resisted as it may exaggerate some factors, neglect others, and produce unsatisfactory results. It is far better to proceed methodically and in an orderly way, and thus ensure that every concern is given its proper due (see below).

BASIC PROCEDURES FOR THE BIOETHICAL REVIEW OF A PATIENT'S CASE

The patient should:

- have an opportunity to be heard
- be encouraged to bring an advocate to the Committee meeting where the patient's case will be discussed
- receive an account of the Committee's advice, recommendations or decisions

When Health Care Ethics Committees begin to review particular cases (see Appendix III for an example of a case consultation form), the first thing they usually want to do is comment on the substantive bioethical issues. In their eagerness they may ignore set internal procedures. Yet good procedures facilitate good outcomes. They ensure that topics are addressed in an orderly fashion, that different points of view are expressed, and that courtesies are observed.

Would Committees be better advised to adopt a policy whereby they always seek to obtain patients' points of view, either directly from the patients or through their representatives? Much has been said and written regarding the need to respect each patient's dignity, but this is sometimes construed so superficially that it does not include consulting with him or her on matters of direct concern.

Health Care Ethics Committees' procedures are clearly not adversarial, as is usually the case in a legal setting in court. Rather, the health care community prides itself on being collegial. Still, the interests of health providers may sometimes conflict with the interests of patients, and there is the ever present possibility of misunderstanding. Good procedures can often deter the abuse of power by health care institutions, especially since Health Care Ethics Committees are currently seen as playing a role in the care or healing process to which health care institutions are in principle dedicated (see Appendix III).

Procedures and policies for Committee consultations on patients' cases

There may be an ambivalence characterizing consultations. On the one hand, Bioethics Committees may view their function as generating ethical recommendations. They are aware that in a health care institution where others specialize in technical and medical affairs, the ethical dimension may not always receive a full and sophisticated hearing. On the other hand, Committees may view themselves as engaged in the business of conflict resolution. They may have before them interested parties, each a person of good will, who disagree fundamentally on matters of great importance. Committee members may see it as their task to mediate, as it were, the dispute, so that it may be resolved at least to the partial satisfaction of all concerned.

Once patients and their families access the Bioethics Committee and the Committee determines that the bioethical problems are within its purview, then the Committee is obliged to convey its mediation procedures and internal policies to all those concerned. The Health Care Ethics Committee mediation procedure then continues and can be described by a series of questions that require procedural answers:

1. Who will serve as mediator – the entire Committee or a subcommittee?
2. Other than the patient and/or the patient's family, who will be present at the meeting? How many Committee members will be present?
3. In what order will those present speak at the meeting?

4. Is the discussion recorded? By whom? How should it be documented, filed and stored?
5. How important is Committee consensus as an outcome of the discussion?
6. If the Committee arrives at recommendations, are they ever binding? To whom will the recommendations be conveyed?
7. Who will follow up and determine if the recommendations have been carried out?

Once the consultation session adjourns, the participating Committee members should reconvene and review the consultation/mediation conference. They might pose a few additional questions: Was the mediation effective? Was it appropriate, was there an actual conflict that required mediation in the first place? Were the parties treated fairly and respectfully, irrespective of the outcome? Should any aspect of the mediation procedure be avoided in the future? One possible outcome is that the review of different patients' cases may require different procedures.

In sum, although following specific procedures may not always be as interesting as addressing substantive bioethical issues, Health Care Ethics Committees must not overlook those procedures. If they are ignored, the result, paradoxically, may be judged only in terms of the procedures followed. Such a situation may easily translate into failure to achieve a fair and helpful case consultation.

In this, patients' records are of central importance. These records contain the medical histories, diagnoses, treatments and assessments of patients. Health care institutions have medical records departments with administrative responsibility for all patients' medical records. These records are usually confidential and only authorized personnel have access to them, including Health Care Ethics Committees, which rely heavily upon them in their deliberations. These records figure prominently in the Committees' minutes.

Chairpersons frequently require their Committees' secretariats to prepare and retain two sets of confidential documents: one contains the minutes of all Committee meetings, although the names of particular members may or may not be noted in the minutes; the second set of documents contains Committees' deliberations and outcomes (advice, recommendations, decisions) regarding patients' case reviews. These files, usually kept by the chairperson or the office to which he or she reports, are not usually accessible to patients or their families. This policy is similar to the long-standing policy adopted by physicians following medical consultations in health care institutions, although records of medical consultations are usually retained in the patient's medical record, or even in his or her medical chart. A special request to consult this additional information may be required which effectively precludes the casual chart observer from having easy access to it. An obvious difficulty arises if secretariats retain separate records: additional procedures and policies for accessing these files will be required; therefore, the fact there exist two sets of records must be recorded. Here chairpersons run the risk of failing to

ensure that each person with a need to know does in fact know where to locate these records. Overly complex procedures, in this context, could easily compromise the confidentiality of the Committee's records.

There is apparently no consensus regarding whether discussions and recommendations of all patients' cases reviewed by a Committee should be included in its records. Some argue that to enter all patients' case reviews in their medical records creates more problems and may require more procedures than considering each case on its own merits. Since a newly established Health Care Ethics Committee needs to acquire institutional credibility, it should not be perceived as the 'ethics police', a tribunal passing final judgement and pronouncing 'ethical verdicts'. It has been suggested that a Committee should record and file only those case reviews that meet specific criteria. What purpose would be served by a policy to record all case reviews? Furthermore, there is already great consternation over the requirement to maintain the confidentiality of patients' records and charts, especially since they are easily electronically transmitted and far too often accessible on the Internet. It has also been suggested that to require written entries of case reviews in all patients' records could reinforce an unfortunate stereotype and misunderstanding of the functions of Health Care Ethics Committees, i.e. that they make not only bioethical but also medical decisions that must be acted upon – which they are not empowered to do. In short, Health Care Ethics Committees would no longer be regarded as platforms where bioethical issues can be discussed in a constructive and non-threatening setting.

To assuage the anxiety that sensitive and possibly threatening information might fall into the wrong hands, the Committee chairperson may elect not to disclose sensitive material, since he or she may deem it potentially harmful to the patient if such information is disclosed without at least informing the attending physician. Should a similar policy be adopted by Health Care Ethics Committees with respect to patients' bioethical case reviews? If case reviews focused on interpersonal relationships among family members, members of the hospital staff, or others, there is a potential for litigation based on a variety of complaints. In the end, the records of patients' case reviews are part of their medical history, and should be made available only to those persons who have a legitimate need to access their contents.

PROCEDURES FOR HEALTH CARE ETHICS COMMITTEES TO CONSIDER WHEN THEY ENTER CASE REVIEWS IN PATIENTS' MEDICAL RECORDS

Patients' case reviews should:

- be accurate, descriptive and analytical
- be clearly written to avoid possible misunderstandings
- avoid emotionally judgemental terminology

2.4. Research Ethics Committees

Procedures and policies for accessing the Committee

Unlike Health Care Ethics Committees, clinician-scientists in research centres and health care institutions who intend to conduct research with human participants constitute a well defined group with similar backgrounds; they frequently seek access to Research Ethics Committees in their institutions and research centres. Physicians and other health professionals, whose primary responsibility is patient care, generally do not seek access to a Research Ethics Committee. The exception is reflected in situations where practising clinicians who are caring for critically ill patients – when all other treatment options have been tried and failed – seek approval from a Research Ethics Committee to administer an experimental drug, vaccine, or new surgery that has not yet been approved for general use by the Member State's authoritative body.

Procedures and policies for reviewing the ethics of proposed scientific and clinical research

Chairpersons of Research Ethics Committees usually convene monthly meetings, but it is no longer unusual for Committees to convene more frequently, given that human research has dramatically increased among developed States. As is the case with other forms of Bioethics Committees, the chairperson usually prepares an agenda two weeks or more in advance of each meeting and distributes it to the members. Members of Research Ethics Committees are obliged to review carefully a growing number of research protocols that describe their proposed clinical investigations in great detail. Often, researchers will also be required to provide additional supporting forms and material.

One should not ignore the researchers' perspective, especially in today's research milieu. They often face a very serious problem – some even consider it a crisis: how long will a Research Ethics Committee's review process take? The Committee, of course, will intend to be careful and thorough, and a proper review cannot always be done quickly. Yet researchers see a delay as interrupting the entire project, perhaps jeopardizing funding, giving competing researchers an advantage, and causing avoidable suffering or death among patient-participants who must wait for the approval of new drugs, vaccines, surgical procedures and implantable devices. Indeed, so much is at stake that suspicions – 'Is this delay actually an effort to inhibit my project?' – and personal animosities among scientist-clinicians – 'Is every research proposal scrutinized as thoroughly as mine?' – frequently arise, greatly complicating matters. Scientists are not automatons, immune from normal human responses.

So far, the only new procedure that has significantly reduced researchers' grant application time, is the submission of proposals for bioethical review after, rather than

before, they undergo scientific review, since the scientific review process usually eliminates many protocols. With fewer protocols requiring bioethical review, the reviews are processed more quickly. Researchers may also expedite matters by designing proposals that are simpler to review. Unnecessary complexities and potential conflicts of interests should be eliminated before the proposals are submitted.

Since every research protocol that involves human participants requires that investigators obtain the informed consent of the participants before the trial begins, probably no aspect of human research has received closer scrutiny by Research Ethics Committees than informed consent. Research Ethics Committees' informed consent procedures and policies sometimes originate from national, regional, or local regulations or from their own health care institutions.

For example, UNESCO's Universal Draft Declaration on Bioethics and Human Rights (Article 6 – Consent) states:

a) 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.

b) 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. The 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, in particular in Article 27, and international human rights law.

c) 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.

An example of a Research Ethics Committee, not established at the local level, is the Central Committee on Research involving Human Subjects (CCMO), established in The Hague in the Netherlands (see Appendix II A).

Whatever the authority (national, regional or local), the spotlight has focused on the content of consent forms. Unfortunately, Research Ethics Committees have not always been effective in improving the process of obtaining research participants' consent. Procedures for periodic monitoring of the content of consent forms, wherever they are employed, have simply been inadequate. To avoid preparing consent forms that reflect a

failure to protect potential participants' interests, e.g. that they are not subjected to greater than minimal risk (except by participating in particular protocols which ethically justify that participants take greater than minimal risk of harm to themselves), specific procedures should be followed by principal investigators.

It would be worthwhile to authorize Research Ethics Committees to conduct internal audits of consent forms used by their institutions' investigators. Should Committees initiate a process that would authorize persons competent to review clinical research directly to observe the researchers' solicitation of participants? Would this procedure be judged too restrictive or unseemly, or would it be taken as only minimally intrusive? Should periodic reviews of human research records be authorized? Whichever audit procedure or policy might be adopted with the express purpose of improving the effectiveness of informed consent as a mechanism for protecting participants in research, specific questions could be posed to the investigators and/or members of their staff.

QUESTIONS TO IMPROVE THE EFFECTIVENESS OF OBTAINING PARTICIPANTS' INFORMED CONSENT BEFORE CONDUCTING CLINICAL RESEARCH TRIALS

1. Who recruited the potential participants? How were they recruited? What criteria were used?
2. Who solicited their informed consent? How was it solicited?
3. Where and when was the consent solicited? Was the potential participant fully apprised, in sign terms he or she could understand, of the risk of harms and possible benefits involved?
4. Was the consent form signed by the potential participant?
5. Was there a witness when the potential participant read and signed the consent form? If so, who was it?
6. Was the witness qualified, and did he or she have a vested interest – or, more worrisome, a conflict of interests - in the research going forward?
7. Would participants be better protected from adverse effects if well trained and experienced research intermediaries were available and assigned to serve as buffers between the research team and the review body charged with approving the bioethical design of the research protocols?
8. What are the operating and hidden costs of committees' reviews? Have they been made known to all the stakeholders?

In short, this complex multi-layered process involves not only the review of (1) scientific and (2) regulatory, but also (3) bioethical design (including the consent form) of all research proposals involving human participants (see Appendix IV).

Procedures and policies for conducting collaborative scientific and clinical research trials in host Member States

Today, in a number of Member States, a good deal is known about the procedures, operations and internal policies of Research Ethics Committees in addition and in contrast to the

substantive bioethical issues they have identified and addressed. This is not the case, however, in a large number of States, where Research Ethics Committees may not have been established. Only recently have States begun to intensify their efforts to initiate internal procedures and adopt policies in order to cooperate with researchers from other States. Other States already have ample resources and the required experience to conduct clinical research trials in host States, though they usually require the participation of citizens of the host States in these studies. Rather recently, attention has focused on the pharmaceutical industry, the principal sponsor of international human research, though a number of Member States' governments have also provided support for biological/biomedical, behavioural, and epidemiological research.

There is a growing consensus that if international research is to continue, bioethical review procedures must be in place in all States concerned, not only to protect the host States' research participants from various forms of exploitation, but also to pave the way for making new, safe and effective drugs, surgeries, vaccines and devices that are affordable and available to the people of the host States and elsewhere. To begin to address this objective, some governments have directed sponsors of human research trials as well as clinical researchers to become involved in enhancing the capacity of Research Ethics Committees in all Member States to conduct not only the scientific and regulatory review of research protocols, but also the bioethical review of all collaborative international research.

Furthermore, several States have adopted policies at the national level of government. These policies require government review of the ethical standards of a diverse group of Committee members as well as of procedures for conducting research in a host nation; such procedures must be at least equivalent to those effective in the State where the research began. It is now clear that host States should have established Research Ethics Committees (or some other bioethical review mechanism) before additional international research protocols are begun. At present, there is ongoing debate as to whether all States concerned should review protocols proposed by only one State to determine their moral justification, and to disapprove or request that they be revised if they are not ethically acceptable.

A review of existing documents on the topic suggests that, at the very least, the following internal policies should be adopted by research review Committees in all States as soon as possible:

1. Provide assurance that researchers are not only familiar with but also fully understand the local cultural norms and moral traditions of host States' participants.

2. Ascertain that the research protocol is feasible to conduct in the host States.

3. Establish a process to assess whether potential participants have been recruited fairly, e.g. equitable gender and race distribution.

4. Formulate appropriate measures, as a result of meetings between researchers of all States

involved, to ensure that potential participants are informed of the relevant possible harms and benefits of the study – without, however, creating information overload or excessive disclosure.
5. Evaluate potential participants' claims that they understand the risks and benefits of the trial.
6. Ensure that participants are not coerced and view themselves as volunteers, free to decide whether to participate in research.
7. Ensure that participants understand the rewards and benefits, if any, which may derive from successful trials.
8. Work to develop what some now call 'capacity-building' in host States – enabling, in time, bilateral collaboration as a consequence of further education.

Once the Research Ethics Committees in all States have determined that their internal procedures for reviewing research protocols are equitable, this alone could encourage credibility among the people of host States, particularly those who have not yet been solicited or recruited to participate in human research trials. In this regard, it is extremely important that patient-subjects' medical records not be compromised. Their confidentiality is expected to be maintained and, if this were breached for reasons of mere expedience, enormous credibility problems would ensue (see below).

PROCEDURES AND POLICIES TO ENSURE THAT PATIENT-SUBJECTS' MEDICAL RECORDS ARE NOT COMPROMISED

1. Indicate that health professionals have a duty to (a) maintain the confidentiality of all patients whose medical records are being accessed for research purposes, and (b) guarantee that patients' anonymity will be protected, especially if the researchers intend to publish their results.
2. Require specific procedures to be established for researchers who plan to access patients' records that have restrictions, i.e. researchers must not violate any restrictions in application at the time of initial collection of the records or information.
3. Require epidemiologists to participate in assessing the risk of harm to patients whose records they plan to access in order to acquire specific information.
4. Include a set of procedures, e.g. the use of codes and other identifiers not linked to patients' names, to protect and safeguard the confidentiality of patients' medical records.
5. Include procedures for removing any links to patients' identities.
6. Require a well-documented procedure to acquire patients' consent, where feasible, before epidemiologists or members of their staff access patients' medical records and other confidential documents when intending to conduct epidemiological research.

Research Ethics Committees might also consider forming focus groups whose participants could include a diversity of perspectives – ethnic, cultural, religious, legal and scientific. Those who participate in the focus groups should be able to identify several salient issues, particularly regarding the ways in which the reviewers of research proposals go about their task. It is still not unusual to discover that many researchers have never visited a host State, and thus are unfamiliar with its people and their traditions, customs and culture. Adequate communication under such circumstances may be problematic, with consequences for obtaining a truly informed consent from potential research participants.

Furthermore, it is far more likely that members of a Research Ethics Committee in a host nation will raise issues that few members on a Research Ethics Committee from an another State would even consider: How will the results of the research, if successful, be of use to local people? If actual treatments result from these studies, who benefits, and in what ways? Will the benefits be made available to them on terms they can afford?

Procedures and policies for avoiding misconduct and improving and sustaining research integrity by scientist-clinicians who conduct human research

(a) Procedures and policies to avoid conflicts of interests by scientist-clinicians who conduct human research

Bioethics literature is replete with publications that attend to the public's growing concern, in a number of Member States, that researchers may be tempted to succumb to a conflict of interests.

One ubiquitous oversight, however, is that not too many people can clearly explain what precisely is meant by the expression 'conflict of interests', though most sense it when they see it. This, in part, is due to the fact that if anyone, especially a researcher, has such a conflict, there must be at least two interests; how else to account for a conflict? The plural, 'interests', is not merely a grammatical point, but enables this concept to be more readily understood.

If we observe what we understand to be a conflict of interests, we should be able to distinguish clearly between the two interests, and then determine whether the individual has a conflict for example, others' safety, health or well-being may be compromised. Most conflicts of interests have to do with money; some have to do with prestige and enhanced reputation; still others with professional advancement.

Consider the following situation:

A pharmaceutical representative invites a physician to recruit his patients to participate in clinical research trials as subjects in his company's search for more efficacious and safe drugs. In recognition of the physician's efforts, the sales representative offers to pay the physician for each patient-subject recruited, to include him in future recruitments, and to

make him a member of the research team. The salesman also promises to provide drugs at reduced prices, which the physician can then sell to his patients.

What interests are in conflict here?

1. The physician has an interest in safeguarding his patients' interests.
2. The physician has an interest in increasing his income.
3. The physician has an interest in participating in useful and prestigious research.

The conflict of interests in danger of arising here is that the physician will be more attracted to the promise of additional income or prestige than to his patients' well-being. Will these inducements bias the physician's recruiting and prescribing patterns at the expense of his patient's best interest – getting well or staying well? Even the semblance of a conflict of interests may be harmful. For it would undermine the physician's credibility.

Research Ethics Committees are in a position to initiate procedures that will lead to internal policies to avoid researchers and practising physicians giving even the appearance of conflicts of interests.

1. Committees can formulate clear and explicit rules to guide researchers' conduct.
2. Committees can publicize these rules and educate researchers as to their importance. They can organize conferences and retreats, create task forces, and in some cases require the participation of key players – researchers, practising physicians, residents and others. In addition, members of Committees can prepare short position papers on the subject of conflicts of interests for dissemination and discussion.
3. Committees can investigate allegations of conflicts of interests and issue recommendations.
4. Physicians who serve on Committees, in collaboration with physicians who practise in the local community, can arrange special joint sessions and invite competent advisors and scholars to provide ethical guidance to these physicians, who may become involved in clinical research and who therefore should be required to participate in formal educational programmes in research ethics and research integrity. In time, perhaps, they may become certified in their new role.

This hypothetical example is particularly relevant in today's health care milieu, since a good deal of attention is now being paid to the activities and decisions of the extensive and powerful pharmaceutical industry. Those within the industry are keen to avoid giving even the appearance of conflicts of interests. Nonetheless, if this problem is not soon addressed across the industry and throughout the medical profession, the public's confidence will continue to erode.

(b) Gag clauses in clinical-trial agreements and the need for ethico-legal standards between research sponsors and investigators

Few today argue that the public, which often generously supports biological/biomedical, behavioural and epidemiological research, does not significantly benefit from research sustained by private and public sponsors. Unless informed by the media or marketers,

however, the public remains unaware of the results of clinical trials and thus dependent upon others to safeguard their interests. These others – academics, government agencies, scientists, clinicians and journalists – can only perform this function if they are granted access to pertinent information. But sponsors, seeking to maximize sales, protect proprietary secrets and minimize competition, may have powerful incentives to keep some of this information to themselves. This has led to the appearance of gag clauses in research agreements between industry sponsors and scientific and clinical researchers.

A gag clause is a restrictive contractual provision included in a legal clinical-trial agreement that attempts to restrict researchers from divulging certain kinds of information. Critics fear that these agreements invite abuse, as vital information may be suppressed because the sponsor considers it unwelcome, perhaps because it reflects unfavourably on issues of safety or efficacy. This is a classic example of a gag clause posing conflict of interest problems, as the financial interest of sponsors beats the sponsors' interest in the welfare of those who depend on their products. These critics argue for creating ethico-legal standards that would govern disclosure and command a consensus of all interested parties.

But what ought these standards to be? Sponsors, seeing the information as their property, insist on their right to control its dissemination. If their investment of time, money and effort does not grant them this entitlement, their incentive to undertake the research that may benefit all of humanity would be seriously undermined. Patent and copyright laws ensure the integrity of intellectual property, and gag clauses, it is said, belong on this list.

Critics retort that the opportunities for abuse posed by gag clauses do not serve the public and that even if abuses do not actually materialize, gag clauses will engender a suspicion of abuse that will erode public confidence in the sponsors and their products, which may reduce government support for research, provoke investigations of researchers and otherwise induce government to act in unproductive ways.

A series of critical questions have been raised: Should sponsors have the authority to control, store and own databases and information (i.e. intellectual property) needed both by researchers appointed to academic medical institutions and who work in the private sector as well as by government-supported scientists? Should sponsors have the authority to include their statistical analyses in researchers' manuscripts prior to publication? Should sponsors retain the right to curtail information-sharing among research institutions, even when it holds great promise? Is it not the case that both researchers and sponsors are accountable to the public? Finally, will the insertion of gag clauses by sponsors – that at the very least tend to undercut transparency – also encourage the public to lose confidence in and come to distrust pharmaceutical firms and even government sponsors when the results of clinical trials become public?

These questions call for answers. Once again, Research Ethics Committees may need to

take the lead by adopting new procedures and establishing new internal policies to address the negative consequences of gag clauses. There follow five suggestions of new procedures that could be adopted.

1. Since Committees, usually established at the local level of government (but also at the national level in some Member States) must approve not only the scientific design of the protocols they review but also the bioethical design of the studies if researchers are to receive funding, they could – if they collaborate – require researchers to have full access to the databases of their trials, not only at the end of the trials but during the data acquisition phases as well. This could serve to curtail the authority of private and public sponsors who may seek to manipulate databases; such action could also assist researchers in disseminating (sometimes even sharing) the databases derived from clinical trials.

2. Chairpersons of Committees could take collaborative action to influence the editors of science and medical journals to require that the authors responsible for clinical trials formally accept full responsibility for conducting the trials. In addition, these influential editors – who serve as buffers between sponsors and researchers on the one hand and their readership on the other – are in a strong position because they may refuse to publish the results of research whose authors and sponsors fail to adhere to stringent ethico-legal standards and guidelines.

3. Committees could forbid sponsors of biological/biomedical, behavioural and epidemiological studies from placing any condition or restriction on researchers when drafting and publishing the results of their research in professional journals or other media; sponsors would not be allowed to censor, delay, limit or prohibit publication, except in rare cases with Committees' prior approval.

4. Committees could work to ensure that databases and knowledge derived from ongoing multi-centred trials be shared. At times, this may serve to protect those who participate in the clinical trials – participants in the study groups and in the control groups.

5. Committees could elect to serve as mediators between sponsors and researchers, assisting them in establishing ethico-legal standards for implementation and inclusion in clinical-trial agreements that affect both sponsors and scientist-clinician researchers.

(c) Procedures and policies to avoid fabrication, falsification and plagiarism by scientist-clinicians who conduct human research

Research Ethics Committees may also be asked to deal with charges of fabrication, falsification and plagiarism. These are deviations from ethical norms that have long been accepted within the scientific community when designing, proposing, conducting or performing, presenting, reviewing, reporting and documenting research results. Among other tasks, well established basic and clinical researchers, as well as students pursuing careers in the basic sciences and clinical disciplines, review patient-subjects' cases and research trials that may involve issues of researchers' integrity.

As these charges may have serious consequences for the institutions and the accused, great care must be taken to ensure that Committees' procedures are well understood and conform to generally accepted canons of fairness. It is essential, therefore, that the procedures not be ad hoc or improvised, but instead be thoroughly formulated with expert legal advice in a time of calm. The offences must be defined so that researchers can understand their rights and obligations, and the procedures to be followed in the hearing should be explicit and easy to follow. To the extent possible, opportunities for procedural disputes and misunderstanding should be eliminated, so that the focus may be wholly on the substance of the case.

Research Ethics Committees should be empowered to seek testimony from witnesses, obtain documentary materials, and call expert consultants. The accused must be afforded an opportunity to confront his or her accuser and refute the charges against him or her. In all this, transparency is absolutely essential, even though some of the parties may fear the consequences of disclosure.

It is also vital that the process be speedily dealt with. Reputations once damaged may never recover, and the accused is entitled to move quickly to salvage his or her good name. Equally, if misconduct has occurred it should be promptly punished and its victims not made to wait unduly for compensation and apology.

The object should be to devise procedures that deter wrongdoing, provide an opportunity for the accused to regain his or her reputation, and offer the victim compensation for suffering.

ALLEGATIONS OF RESEARCHERS' MISCONDUCT USUALLY INVOLVES FOUR GROUPS

1. Clinician-scientists and members of their staff
2. Those who report or reveal alleged misconduct - so-called 'whistle-blowers'
3. Participants in research about whom questions of propriety may have been raised
4. Those who determine the validity of the allegations

Some observers believe that Research Ethics Committees are not the proper venue to settle charges of research fabrication, falsification or plagiarism. They contend that these Committees simply do not have the time or skills required to review allegations of misconduct. Institutions also fear that since Research Ethics Committees, like other Bioethics Committees, include lay members, so-called 'outsiders', the charges will not be kept private and the institutions' reputation will be damaged.

There is a growing consensus, however, that principal researchers must be held accountable and that Research Ethics Committees – or Committees created specifically to address the problem – must take on the task. Notwithstanding the presumption that experienced life scientists and researchers already fully appreciate the basic norms that govern their professional work, self-

education remains the key to ending, for example, the fabrication or falsification of data entered in patients' or research participants' records.

RESPONSIBILITY AND ACCOUNTABILITY OF RESEARCHERS

Did the researcher

1. follow proper procedures when selecting the members of his or her research team?

2. see to it, through the creation of educational in-service bioethics programmes, that staff members were properly instructed in research ethics and research integrity *prior* to participating in clinical research?

3. properly implement the research protocol, e.g. establish adequate procedures to obtain potential participants' informed consent?

4. establish a system of audits to maintain accountability for recording the data acquired during the investigation, and for the content of any publications authored by the members of the research team? Were all the listed authors actual authors?

5. remain current with respect to monitoring the various aspects of the protocol?

6. appoint a member of his or her team (or someone outside the team) to serve in his or her absence, should the well-being of participants become jeopardized?

The principal researcher is administratively responsible for the project, and may be held accountable for its flaws. The foreknowledge that he or she will be held accountable will certainly encourage him or her to root them out. At the same time, however, large projects involving many subordinates at various research sites make detailed supervision impossible, and sometimes even the most rigorous efforts to deter misconduct will fail.

(d) Procedures and policies to avoid extremely serious ethical violations that may occur before, during or after conducting human research

Research integrity may also involve the failure to meet other serious material, legal requirements governing research with human participants. It includes but is not limited to unethical biomedical research, such as deceiving human participants, members of the scientific community and the public, and violating patient-subjects' privacy and confidentiality, including deliberate violations of regulations and other acts deemed fraudulent. The traditional view that fraud is rare has been displaced by the worry that it has simply often gone undetected. As one researcher put it, fraud is not perceived as the work of a few 'bad apples', but rather as the 'tip of the iceberg'.

What can be done by way of establishing procedures and policies to avoid researchers' misconduct? Some procedures have already been established to deal with serious allegations:

- clearly define misrepresentation and fraud, and distinguish them from unavoidable or good faith error;

- educate scientists and clinical researchers as to these policies;
- vigorously enforce these policies, while offering protection and incentives for 'whistle-blowers'; and
- hold responsible principal investigators for abuses that occur on their watch.

RESEARCH ETHICS COMMITTEES' DUAL MISSION

Protecting Human Research Participants

Sustaining Research Integrity

When and in what manner should institutions notify the public of misconduct? Should they report the allegations? Wait until formal hearings have begun? Report only the final findings? Report the findings only if they are a conclusion of guilt? Institutions have their reputations to protect, and the temptation to secrecy may seem overwhelming. But they would do well to acknowledge that misconduct cannot always be hidden, and that if others publicize it – and point to the institution's efforts to hide it – the outcome may be disastrous. Far better to be open and judicious from allegation to resolution. Such an approach might convey the impression of the institution as fair and vigilant and, under the circumstances, that is probably the most it can aim for. In order to ensure this result, institutions should be required to disclose incidents of alleged misconduct and the results of their investigations. Their public credibility demands no less.

In short, allegations of research fraud, beyond fabrication, falsification and plagiarism, proven or not, should initiate much closer scrutiny than would normally be required in routine reviews of the scientific, regulatory and bioethical design of research. Institutions should establish formal rules and regulations governing research fraud, rules and regulations which when breached incur severe penalties – including eliminating the researcher and possibly others from eligibility for funds to continue to conduct research with human participants.

Finally, there is the matter of researchers using deception as part of their experimental design, thus deceiving research participants. This practice has generated considerable controversy, principally because many researchers surveyed about deception in science – particularly in social science – view it as ethically acceptable, whereas others have judged it ethically objectionable. Some define 'deception' as the deliberate withholding of information to mislead research participants or patients. The search for new, generalizable knowledge – said to be the hallmark of biological/biomedical, behavioural and epidemiological research – has led some to violate the dignity of research participants; that much is clear. What remains unclear is whether the second form of deception causes more serious harm when intended to further the careers of researchers and their self-interests. Most would answer with a carefully qualified 'yes' in the absence of further evidence to the contrary.

In the drive to deter and punish abuse, however, it is vital to remember that these efforts have their costs. They consume time, money and effort that might be spent more productively elsewhere: they generate red tape that basic scientists, clinical researchers, and institutions will find burdensome; and they will operate imperfectly, so that some innocent parties will be found guilty and some guilty parties exonerated. The more vigorous the fight against abuse, the higher the costs. Hence, the fundamental question that must tower over particular issues or controversies is how the balance ought to be struck. This question should be addressed openly and fully before subsequent subsidiary questions or specific allegations are tackled.

Part III

EVALUATION OF BIOETHICS COMMITTEES' PROCEDURES AND POLICIES, METHODS OF DOCUMENTATION AND ADMINISTRATIVE COOPERATION WITH SECRETARIATS

1. Evaluating formally and informally the procedures and policies of Bioethics Committees

Bioethics Committees continue to proliferate, though their impact upon national, regional and local health policies, as well as clinical practice and clinical research has not been rigorously evaluated. One reason is that chairpersons and Committee members tend to believe that such evaluations are unnecessary. Clearly, a disinterested party is required to gather the data, conduct the analysis and report the findings. Furthermore, after some procedures and policies have been adopted and followed, they also tend to become accepted practice and attempts to evaluate them rigorously may be rejected for a variety of reasons. Until such an evaluation can be conducted, however, self-evaluation, with its own potential conflict of interests, will remain the rule. Bioethics Committees, therefore, remain vulnerable to many of the same allegations they were created to address.

With respect to evaluating the procedures and policies of all four forms of Bioethics Committee, there is little doubt that there are straightforward practical difficulties, such as lack of funds to support the self-evaluation of the Committees' procedures and policies.

One might begin the process of self-evaluation of a Committee's procedures and policies by seeking to obtain a rough estimate of the number and types of procedures and policies that have actually been adopted. But rough estimates are often misleading, and some procedures and policies might be onerous, demanding too much time of the Committee's members. Ideally, any self-evaluation model that is designed to determine the effectiveness of a Bioethics Committee's procedures and policies, involves comparing them by employing a 'before and after' design and holding relevant variables constant; but this is time-consuming and difficult to accomplish. Candid, rigorous self-evaluation, however, is probably an essential prerequisite for success.

Unfortunately, relatively little interest has been shown by way of self-evaluating how well these Committees operate, and this has limited the prescriptive advice on how to improve these Committees' operations and procedures. Ironically, perhaps, despite the differences between Bioethics Committees in terms of form and level of government, it is likely that these Committees actually share a standard set of procedures and policies. In time, perhaps, a single self-evaluation or self-assessment tool will be designed by Bioethics Committees to assist their members in evaluating not only the establishment of their procedures and policies, but their overall effectiveness as well.

2. Cooperating with institutional secretariats to sustain permanent, statutory Bioethics Committees

One excellent example of a permanent secretariat is the French Government's *Institut national de la santé et de la recherche médicale* (INSERM), which continues to provide technical and administrative support to France's *Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé* (CCNE), created by the President of the Republic in 1983. INSERM makes available its ethics of health and life sciences documentation centre as a resource for the Committee.

France's CCNE, having statutory status, continues to play a central role in the nation's deliberations on bioethical issues, at times even involving itself in day-to-day bioethical controversies arising in French hospitals and the courts. Indeed, the CCNE's formal opinions and findings are extensively covered by newspapers and journals, which provide reportage and commentary even on its more philosophical deliberations.

One internal policy of CCNE is that its minutes do not reveal the identity of those who make oral remarks; another is that it not only considers topics of its own choosing, but questions can be brought to it by government officials, by the presidents of the two chambers of parliament and by public institutions involved in human research. A third CCNE policy is a system of specialized subcommittees to address particular topics and report back to the CCNE as a whole.

Part IV

EXTENDING THE INFLUENCE OF BIOETHICS COMMITTEES AND ESTABLISHING PROGRAMMES FOR CONTINUING BIOETHICS EDUCATION

Like many innovations, Bioethics Committees may attract support in principle but indifference or even hostility in practice. It is hard, after all, to oppose efforts to make the institutional practice of health care more ethical. But because these efforts necessarily challenge reigning assumptions and habits and the individuals and structures that benefit from them, they will

inspire objections. As these objections may take the form of seeking to limit the Committees, it is vital that their advocates consider how to extend the Committees' influence.

1. Advising and relating to elected and appointed officials

Bioethics Committees exist and function in a larger administrative and political world in which elected and agency officials may shape their mandates and authority and affect their public image and support. In order to prosper, therefore, Committees may decide to reach out to these influential officials. Here, it would be prudent first to obtain approval from the Committees' home institutions. Once permission has been received, the Committees may proceed.

Initially, their goals may be merely to remind the officials of the Committees' existence and tasks, and to generate sympathetic understanding. This might be pursued, first, through informal meetings where connections may be made at a human level and rapport established. The next step might be more formal, perhaps inviting officials to a seminar or conference. As officials and Committee members learn more about each other, develop trust and perhaps become friends, the interactions may increase, maybe even becoming regularized. Eventually, harmonious and mutually advantageous relations ensue.

Success, however, is by no means guaranteed, and as the Committees are more needy and vulnerable, the responsibility for progress must rest with them. Busy officials may ignore the Committees; or the officials may have pre-existing relationships with the Committees' foes, predisposing them to opposition to the Committees. These problems must be acknowledge by Committee chairpersons, and approached with great delicacy and circumspection. If the problems are overcome, the gains may be substantial.

2. Relating to scientists and health care professionals

Committees will want to reach out not only to officials but also to scientists and health professionals. Much of the influence of Bioethics Committees depends upon their appearance, for they lack powers of coercion. If they are deemed competent, serious and responsible, if their members are regarded as intelligent, well-informed, and easy to work with, they will be taken as fully legitimate bodies entitled to affect the conduct of others.

The key actors in molding this appearance are often scientists and health professionals. For they alone can claim an expertise over the complex and technical problems that the Committees consider. If they think highly of a Committee, in a sense they give it their seal of approval, certifying it as, in their professional opinion, worthy of respect.

In recognition of this, Committees will seek to develop good relations with scientists and health professionals through informal meetings, seminars, conferences and so on.

As they work to build support, however, Committees must not lose sight of a pair of basic concerns. First, the expertise of scientists and health professionals does not extend to bioethics.

They, of course, may not perceive their own limitations, taking for granted that their technical knowledge and years of experience render them competent in ethics as well. Second, in cultivating the good opinion of scientists and health professionals, the Committees must not relinquish their own independence. If cultivation takes priority over ethical considerations, the Committees will become mere conduits for the scientists and health professionals' views, and the Committees' very reason for existence will have been sacrificed. As with developing appropriate relations with officials, reaching out to scientists and health professionals demands a stern commitment to ends and a subtle flexibility as to means.

3. Relating to the public and the media

Bioethics Committees, especially those established at the national level of government and within health professional organizations, can often benefit from media exposure, provided they have adopted procedures and policies in full cooperation with their secretariats.

But Committees should be prudent. The press may not be well informed on bioethics, or may be under such urgent time constraints that mistakes are hard to avoid. And the press delights in conflicts, often magnifying disputes or construing statements in order to maximize controversy. For it is controversy, far more than substance, that attracts audiences. Often, Committee members – intelligent, learned and accustomed to deference – have found themselves overpowered by experienced reporters.

Yet the answer is not to avoid the press, but to cultivate it in order to produce a steady stream of articles that educate the public and that, if trouble emerges, the Committee will have accumulated some trust and goodwill which might prove advantageous. In this regard, Committees should try to make use of their institution's secretariats and press office, which can provide them with practical advice and personal contacts. Press briefings, seminars, conferences and informal meetings may also aid in creating an atmosphere of friendship and understanding. Care should be taken to educate reporters so their articles do not mislead the public. Though not expert in bioethics or health care, reporters are trained to grasp a few central themes and reshape them for mass consumption. They should not be addressed with jargon nor patronized as ignorant, but rather approached as skilled professionals in their own right, who perform the vital function of communicating the Committees' work to the public. Good relations with the media can pay high dividends.

Today's Bioethics Committees need to establish procedures and policies that will enable them – particularly through their publications – to avoid exacerbating public misunderstanding. These procedures and policies should also be adopted by Health Care Ethics Committees and Research Ethics Committees established at local and regional levels. Clinical research centres and health care institutions at the local level may become more 'user friendly' if local health

care institutions' Bioethics Committees adopt appropriate procedures and policies, and carry them out.

A group of Committees, for example, may jointly convene local conferences open to the public; media professionals may be invited to participate in presentations and open discussions. Small group sessions followed by plenary sessions may enable members of local Bioethics Committees to engage media specialists directly and in public view, decreasing the likelihood that misunderstanding and confusion will follow in their media coverage. The reverse is also true: chairpersons and members of Bioethics Committees can come to understand how the public thinks when the media report accurately and straightforwardly; this can bear on future discussions and decisions taken by Committees.

4. What Bioethics Committees need to know: preparing future chairpersons and members

Great care taken in recruitment ensures that members of Bioethics Committees will be intelligent, conscientious and expert in their respective fields. What it does not ensure is that members will be expert in bioethics. Indeed, we may assume that few members will have had formal training in the field, and many will never have thought systematically about this domain of issues and specific bioethical dilemmas.

4.1. General Topics in Bioethics for Committee Members

The first task, then, is to induce chairpersons and Committee members to view the problems before them not from their familiar perspectives – scientific, clinical, financial, administrative – but rather from a bioethical perspective. There are, of course, a multitude of ethical perspectives and theories, and the study of bioethics can easily consume a lifetime. Committee members, however, are not aiming to become professional bioethicists, and so their preparation need not be comprehensive.

What members must grasp, however, are a number of core bioethical concepts. Individual autonomy (popularly, the right to self-determination) is a fundamental postulate in many societies, where it is celebrated as freedom. Yet in health care settings, the individual's capacity to deliberate, to choose and to act may be compromised, undercutting the precondition for his or her autonomy. Under what circumstances and to what extent – Committees often inquire – does the individual retain autonomy? A second concept is rights. The term 'rights' is used loosely in ordinary speech, usually as a rhetorical device to assert a claim. Committee members must be taught to reject such usage and to recognize rights as entailing obligations, frequently of considerable weight. A third concept is justice, which should direct Committee members towards the goal of the equitable sharing of risks, burdens and benefits. Finally, non-maleficence and beneficence, often considered in tandem, should alert members to take care that their actions do not generate avoidable harm, but rather promote welfare.

Presented in these terms, the concepts may appear platitudinous. But it is the task of the

chairperson to ensure that the membership comprehends the complexities of these and other bioethical concepts so that they are fully incorporated in members' discourse. It is the ethical dimension, in the final analysis, that justifies the Committees' existence.

4.2. Specific Topics for the Four Forms of Bioethics Committees

Each of the four forms of Bioethics Committees, of course, will confront its own characteristic bioethical issues. Policy-Making and/or Advisory Committees, for instance, since they not only advise government officials, must proceed from a broad vantage point to consider the consequences of proposed policies for the entire society, or perhaps for all humanity. Health-Professional Association Bioethics Committees will concern themselves with ethical standards and practices for their respective health professions. Health Care Ethics Committees will focus on such issues as improving patient care, end-of-life decisions, and reproductive biotechnologies. Finally, Research Ethics Committees, for their part, will attend to protecting participants in clinical trials and research integrity. The bioethical agenda is daunting but Committees must avoid intimidation and get down to the business at hand.

Part V

RECOMMENDED READING

Amdur, R. J., Bankert, E.A. IRB Management and Function. Jones and Bartlette Publishers, Sudbury, MA, 2001.

UNESCO Report of the IBC [International Bioethics Committee] on the Possibility of Elaborating a Universal Instrument on Bioethics. SHS/EST/02/CIB-9/5, Paris, 13 June 2003.

UNESCO Universal Draft Declaration on Bioethics and Human Rights. General Conference 33C/22, Annex, 5 August 2005.

WHO Operational Guidelines for Ethics Committees that Review Biomedical Research: Geneva, Switzerland – Report no. TDR/PRD/ETHICS / 2000.1. (WHO document: http://www.who.int/tdr/publications/publications/pdf/ethics.pdf)

Appendix I

RULES OF PROCEDURE OF THE INTERNATIONAL BIOETHICS COMMITTEE (IBC)

I. MEMBERSHIP

Rule 1 The International Bioethics Committee of UNESCO (IBC), hereinafter referred to as 'the Committee', shall be composed of 36 members, in accordance with Article 3 of its Statutes.

II. SESSIONS

Rule 2 Regular and extraordinary sessions

2.1 The Committee shall normally meet in regular session at least once a year.

2.2 The Committee shall meet in extraordinary session, such sessions being convened by decision of the Director-General or at the request of at least two-thirds of its members, provided that the necessary resources are available.

Rule 3 Convening of sessions of the Committee (Article 5 of the Statutes of the IBC)

3.1 The sessions of the Committee shall be convened by the Director-General of UNESCO.

3.2 The Director-General shall inform the members of the Committee of the date, venue and provisional agenda of each regular session at least 60 days before the opening of the session; in the case of an extraordinary session, members shall be informed, if possible, at least 30 days before the opening of the session.

3.3 The Director-General shall, at the same time, inform the States and organizations mentioned in Article 4 of the Statutes of the Committee, of the date, venue and agenda of each session.

Rule 4 Date and venue of the sessions

4.1 The Director-General, in consultation with the Bureau of the Committee, shall set the date and venue of each session.

4.2 Any Member State of UNESCO may invite the Director-General to convene a session of the Committee on its territory.

III. PARTICIPANTS AND OBSERVERS

Rule 5 The members of the Committee, invited by the Director-General of UNESCO in accordance with Rule 3 above, shall participate in the work of the Committee.

Rule 6 Observers (Article 4 of the Statutes of the IBC)
The States and organizations mentioned in Article 4 of the Statutes of the Committee may attend the sessions of the Committee as observers, on the invitation of the Director-General.

Rule 7 Hearings (Article 4 of the Statutes of the IBC)
The Director-General shall invite specialists and eminent persons designated by the Committee to participate in any hearings organized during the sessions of the Committee.

IV. WORK PROGRAMME

Rule 8 Work Programme

8.1 In accordance with Article 2 of its Statutes, the Committee shall determine its work programme, which will be reviewed at each regular session.

8.2 Subject to any request of the Director-General, the Committee shall recommend the priorities to be assigned by the Committee and the Secretariat to the activities of the Committee.

V. AGENDA

Rule 9 Agenda

9.1 The agenda for the sessions of the Committee shall be prepared by the Director-General in consultation with the Bureau of the Committee.

9.2 The agenda of a regular session of the Committee shall include:

(i) all items and study topics the inclusion of which has been decided by the Committee at its previous sessions;

(ii) all items proposed by the Bureau of the Committee, after consultation with the members of the Committee;

(iii) all items which the Director-General has decided to include.

9.3 The agenda of an extraordinary session shall include only the items for the examination of which the extraordinary session was convened.

9.4 The documents relevant to the items on the Agenda for consideration at a regular session of the Committee shall be distributed to members of the Committee, if possible, before a meeting of the Committee

Rule 10 Addition of new items
The Committee may add new items to the agenda thus established, if so decided by a two-thirds majority of the Committee members present.

VI. BUREAU

Rule 11 Elections

11.1 The Committee shall elect a Chairperson, four Vice-Chairpersons and a Rapporteur who, assisted by the Secretary-General of the Committee, shall constitute the Bureau of the Committee and shall remain in office until the closing of the second regular session thereafter, provided that they remain members of the Committee.

11.2 The Chairperson, Vice-Chairpersons and Rapporteur shall be immediately eligible for re-election only once.

Rule 12 Functions of the Bureau

The Bureau shall be responsible for coordinating the work of the Committee and setting the date, time and agenda of meetings. It shall perform any other function entrusted to it by the Committee.

Rule 13 Duties of the Chairperson

13.1 The Chairperson shall declare the opening and closure of sessions, direct the discussions, ensure observance of these Rules and accord the right to speak. He/she shall discharge any other duties entrusted to him/her by the Committee.

13.2 A Vice-Chairperson acting as Chairperson, in accordance with Rule 14 of the present Rules, shall have the same powers and duties as the Chairperson.

Rule 14 Replacement of the Chairperson

14.1 If the Chairperson is unable to exercise his/her functions during a whole session of the Committee or part thereof, his/her duties shall be carried out in turn by the Vice-Chairpersons following the French alphabetical order.

14.2 If the Chairperson ceases to be a member of the Committee or for any reason is unable to complete his/her term of office, he/she shall be replaced by a Vice-Chairperson, following the French alphabetical order, until the close of the following regular session of the Committee. In this case, the new Chairperson will be elected among the members of the Bureau for a term of office of one year.

14.3 In case Rule 14.2 is applied, a new member of the Bureau shall be elected on the vacant seat for a term of office of one year.

Rule 15 Replacement of the Vice-Chairperson(s)

The provisions of Rule 14.3 shall apply mutatis mutandis to the four Vice-Chairpersons.

Rule 16 Replacement of the Rapporteur

16.1 If the Rapporteur is unable to exercise his/her functions during a whole session of the Committee or part thereof, his/her duties shall be carried out in turn by a Vice-Chairperson, following the French alphabetical order.

16.2 If the Rapporteur ceases to be a member of the Committee, or for any reason cannot complete his/her term of office, he/she shall be replaced by a Vice-Chairperson, following the French alphabetical order, for the unexpired portion of the term of office.

VII. SUBSIDIARY BODIES

Rule 17 Subsidiary bodies

17.1 The Committee, with the agreement of the Director-General, may establish such subsidiary bodies as it considers necessary for the conduct of its business, within the limits of available financial and technical resources.

17.2 The Committee shall define the extent to which the present Rules shall apply to each subsidiary body.

VIII. CONDUCT OF DEBATES

Rule 18 Quorum

18.1 In plenary meeting, a majority of the States members of the Committee present at the session shall constitute a quorum.

18.2 At meetings of subsidiary bodies, a quorum shall be constituted by a majority of the members of the body in question present at the meeting.

18.3 The Committee and its subsidiary bodies may take no decision on any matter unless there is a quorum.

Rule 19 Special consultation by correspondence

The Bureau may be consulted by the Secretariat by correspondence concerning urgent and important measures.

Rule 20 Order of speeches

20.1 The Chairperson of the meeting shall give the floor to speakers in the order in which they signify their wish to speak.

20.2 The Chairperson of the meeting may limit the time to be allowed to each speaker when circumstances call for such a decision.

20.3 The observers referred to in Rule 6 of these Rules may take the floor during a meeting with the prior consent of the Chairperson of the meeting.

Rule 21 Voting

21.1 The Committee shall endeavour to arrive at its decisions by consensus. In the event of a vote being taken, decisions shall be taken by a simple majority of the members present and voting. Each member of the Committee shall have one vote.

21.2 In the event of advice or recommendations to the Director-General of UNESCO concerning possible amendments to the Declaration, for submission to the General Conference, the decisions shall be taken by a two-thirds majority of the members present and voting.

21.3 The phrase 'members present and voting' means members casting an affirmative or negative vote. Members who abstain from voting shall be regarded as non-voting.

Rule 22 Voting by show of hands and roll-call

Voting shall normally be by show of hands, except that any member may, before the voting starts, request a roll-call. The vote or abstention of each member participating in a roll-call shall be recorded in the report.

Rule 23 Voting on amendments

When an amendment to a proposal is moved, the amendment shall be voted on first. When two or more amendments to a proposal are moved, the voting shall take place in accordance with the practices in force at UNESCO.

Rule 24 Voting by secret ballot

All elections shall be by secret ballot unless, in the absence of objections on the part of any of its members, the Council decides otherwise.

Rule 25 Equally divided votes

If a vote is equally divided, the proposal shall be regarded as rejected.

Rule 26 Public nature of meetings

Meetings shall be held in public unless the Committee decides otherwise.

Rule 27 Working languages

27.1 The working languages of the Committee shall be English and French. Statements made during meetings of the Committee in one of these two languages shall be interpreted into the other language.

27.2 The documents of the Committee shall be issued in English and in French.

IX. SECRETARIAT OF THE COMMITTEE

Rule 28 Secretariat (Article 9 of the Statutes of the IBC)

28.1 The Committee shall be assisted by a Secretariat whose members shall be appointed by the Director-General.

28.2 The Director-General or his representative shall participate in the work of the Committee and its consultative and subsidiary bodies. He may at any time make either oral or written statements concerning any matter under discussion.

28.3 The Secretariat shall be responsible for preparing, translating and distributing all official documents of the Committee and shall arrange for the interpretation of the discussions in accordance with Rule 27 of these Rules.

28.4 The Secretariat shall also perform all other duties necessary for the proper conduct of the work of the Committee, including the distribution of all documents during the work of the Committee.

X. ADOPTION, AMENDMENT AND SUSPENDED APPLICATION OF THE RULES OF PROCEDURE

Rule 29 Adoption of the Rules of Procedure (Article 8 of the Statutes of the IBC)8.1 The Committee shall adopt its Rules of Procedure by a decision taken by a two-thirds majority of the members of the Committee present and voting. The Rules shall be submitted to the Director-General for approval..

Rule 30 Amendment of the Rules of Procedure

These Rules of Procedure, except for rules which reproduce certain provisions of the Statutes of the International Bioethics Committee of UNESCO (IBC), may be amended by a decision of the Committee taken by a two-thirds majority of the members of the Committee present and voting, provided that the proposal for amendment is included in the agenda of the session, in accordance with Rules 9 and 10 of these Rules. The modification is submitted to the Director-General for approval.

Rule 31 Suspended application of the Rules of Procedure

The application of certain rules in these Rules of Procedure, except for rules which reproduce provisions of the Statutes of the International Bioethics Committee of UNESCO (IBC), may be suspended by a decision of the Committee taken by a two-thirds majority of its members present and voting.

** Adopted by the IBC at its Fifth Session on 2 December 1998 and approved by the Director General on 21 December 1998. Amended by the IBC at its Seventh Session on 6 November 2000 and approved by the Director-General on 30 November 2000. Amended by the IBC at its Eighth Session on 14 September 2001 and approved by the Director-General on 23 November 2001.*

Appendix II

EXAMPLES OF PROCEDURES AND POLICIES
I. CENTRAL COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS (CCMO): THE NETHERLANDS

Preamble

Upon considering the provisions in Article 14.9 of the Medical Research Involving Human Subjects Act of 26 February 1998, Bulletin of Acts, Orders and Decrees 1998 161, 22588, (hereinafter to be referred to as: the 'WMO'), the Central Committee (hereinafter to be referred to as: the 'Central Committee on Research Involving Human Subjects', for short as: the 'CCMO'), as referred to in Article 14.1 of the WMO, provides for its organisation, insofar as this does not follow from the WMO, and its manner of operation as follows:

Article 1
Designation of the responsibilities of the Central Committee on Research Involving Human Subjects

In addition to the responsibilities arising under the WMO, the CCMO shall have the responsibilities directly arising under the Embryos Act of 20 June 2002, Bulletin of Acts, Orders and Decrees 2002 338, 27423 (hereinafter to be referred to as: the 'Embryos Act').

Article 2
Membership

The Chairman, the other members and the deputy members shall serve in the CCMO in their private capacities.

Article 3
Meetings and reporting

1. As a rule, the CCMO shall meet once a month according to a schedule to be drawn up annually.
2. The Chairman can decide to deviate from the frequency of meetings and schedule referred to in the previous paragraph.
3. Deputy members shall have access to the CCMO meetings, even if they have not been called as deputy members.
4. The Chairman shall convene the meetings and set the agenda. The Secretary shall ensure that the documents are sent.

5. CCMO meetings shall not be public, unless the Chairman believes there are reasons for deviating from this.
6. CCMO's Secretary shall ensure that reports are drawn up of the CCMO meetings.

Article 4
Decision-making

1. Valid resolutions may only be passed in a meeting attended by at least 10 members or deputy members, in which all disciplines referred to in Article 14.2 of the WMO are represented.
2. In deviation from the preceding paragraph, the Chairman shall determine in exceptional cases that a written contribution from an absent Committee member or deputy Committee member shall suffice as well. If the presence of the missing discipline is necessary for the discussion, decision-making shall be postponed until the following meeting.
3. Deputy members attending a meeting without having been called as such shall not be entitled to vote.
4. Every effort will be made to ensure decisions are made unanimously. Valid resolutions may be passed by a simple majority vote. If there is a tie vote, the Chairman's vote shall be decisive.
5. Decisions shall be taken orally, unless, whether or not at the request of one or more members present, the Chairman decides to hold a ballot vote.
6. If, in connection with a situation referred to in Article 10.6 or otherwise, it turns out to be impossible in fact for all disciplines referred to in Article 14.2 of the WMO to be involved in the decision-making, a decision shall not be taken until after an external expert in this missing discipline has been heard by the Committee.

Article 5
Representation of the CCMO

The Acting Chairman shall represent the CCMO in and out of court. He/She may delegate this authority.

Article 6
Hearings

1. Oral testimony shall be taken in a hearing in which at least two members or deputy members are present on the CCMO's behalf.
2. At the request of interested parties or not, the Chairman may determine that the hearing be attended by one or more experts.

3. If it deems this necessary to formulate a judgement, the CCMO may also convene a hearing in other cases besides those which it is required to hold under the General Administrative Law Act.

Article 7
Obtaining advice from external experts

1. The Committee may be advised by other experts besides its own members or deputy members.
2. If experts are engaged to help the CCMO formulate a judgement concerning a certain protocol, the Chairman shall make certain that the expert does not have a direct interest in the particular investigation.
3. In the situation referred to in the preceding paragraph, the particular experts may attend discussions concerning that protocol.

Article 8
Procedures

1. Accreditations
   a. A request for accreditation from a medical ethics review committee shall be made by submitting a completed application form.
   b. The request for accreditation must be filed with the CCMO, Attn: General Secretary.
   c. The CCMO's General Secretary shall confirm receipt of the request.
2. Judgements regarding investigation protocols
   a. A request for assessment of an investigation protocol shall be made by submitting the entire protocol and completing the General Assessment and Registration Form.
   b. The request must be filed with the CCMO, Attn: General Secretary.
   c. The CCMO's General Secretary shall confirm receipt of the request.

Article 9
The Secretariat

1. A Secretariat shall provide support to the CCMO in its work. The General Secretary of the Health Council of the Netherlands shall be the Head of the CCMO's Secretariat.
2. The CCMO shall have a General Secretary, who shall be responsible for the Secretariat's day-to-day management. The General Secretary shall not be a member of the CCMO.
3. The Health Council's General Secretary shall grant authority to the CCMO's

General Secretary with respect to his/her financial and, in part, his/her personal powers regarding the CCMO.

4. In terms of the performance of duties, the CCMO's General Secretary shall be accountable to the CCMO's Chairman; in terms of jurisdiction, the CCMO's General Secretary shall be accountable to the Health Council's General Secretary.

Article 10
Confidentiality and independence

1. The Chairman and the members and deputy members of the CCMO must maintain the confidentiality of information which the Committee obtains in performing its tasks and the confidentiality of which has been indicated explicitly or is implicitly apparent from the nature of the information.
2. The duty to maintain confidentiality shall continue after membership in the CCMO ends.
3. The duty to maintain confidentiality shall also apply to other persons besides those mentioned in paragraph 1 who are involved in carrying out one of the CCMO's tasks.
4. After their membership in the CCMO ends, the members shall destroy the documents in their possession concerning the Committee's work or return the aforementioned documents to the CCMO's General Secretary, who shall then destroy them.
5. The CCMO's members, deputy members and regular experts shall provide a written statement to the Chairman regarding all additional paid or unpaid positions.
6. If the Chairman or a member or deputy member is in any way personally involved in an investigation protocol submitted for assessment, he/she shall not participate – in or outside meetings – in the discussions and the decision-making regarding the particular protocol.

Article 11
Recording and storing documents

1. The CCMO shall record a summary of all investigation protocols assessed by accredited medical ethics review committees and by the CCMO, as well as a copy of the judgement or further judgement provided by the Committee in this respect.
2. The CCMO shall be the custodian of this information.
3. The Secretariat shall ensure that the Committee's documents are stored systematically.

Article 12
Annual Report

Each calendar year before 1 April, the Committee shall draw up a report regarding its work during the previous year. This Annual Report shall be available to everyone for payment of costs.

Article 13
Budget

1. Each year, the CCMO's Secretariat shall draw up a budget for the following calendar year.
2. The budget shall be approved by the Health Council's General Secretary.
3. The CCMO's Secretariat shall account to the Health Council's General Secretary for its expenditures for the past calendar year.

Article 14
Final provisions

1. This Standing Order may be amended by a simple majority of the votes of the Committee's members.
2. The Chairman, members, deputy members and General Secretary of the CCMO may submit amendment proposals.
3. The Committee shall evaluate this Standing Order each year.
4. In cases not provided for by this Standing Order, the Chairman shall decide.

II. NUFFIELD COUNCIL ON BIOETHICS, UNITED KINGDOM

The Nuffield Council was established by the Nuffield Foundation in 1991 in response to concerns that there was no government-sponsored national body in the United Kingdom responsible for overseeing developments in biomedicine and biotechnology. There was seen to be a need for an independent body that could review developments in research, identify ethical issues, make recommendations about policy and stimulate public discussion.

In 2000, following a review of the regulatory framework for biotechnology, the government decided not to create an official national bioethics advisory body, as exists in many countries. Instead, two new commissions were established – the Human Genetics Commission and the Agriculture and Environment Biotechnology Commission. Both commissions have broad advisory roles which include the field of bioethics. The Council collaborates with these various new governmental bodies, both formally and informally, and with the Department

of Health. The Council's independence of government has become increasingly important, particularly as a result of growing public unease about aspects of biomedicine and biotechnology. The Council perceives its independence as critical to help maintain public trust in its work.

Members of the Nuffield Council meet quarterly. During these meetings, the Council reviews recent biomedical and biological advances that raise ethical questions and selects topics for further exploration. In addition to quarterly meetings, the Council considers broader themes at its annual 'Forward Look' meeting. This provides opportunities for discussion amongst Council members about the role of the Council and its methods of working and draws on the expertise of invited speakers. Separate subgroups of the Council also meet to discuss specific matters in more detail, for example finance, future work, membership, education and external relations.

Once the Council has identified a major ethical issue, it establishes a Workshop, Round Table or Working Party to examine and report on the issue. The Council also aims to raise public awareness of the issues considered in its reports and is currently improving liaison with other organizations, both in the UK and abroad.

Appendix III

HEALTH CARE ETHICS COMMITTEES – CASE CONSULTATION FORM STANDARD OPERATING PROCEDURES FOR THE BIOETHICAL REVIEW OF A PATIENT'S CASE

A partial checklist of subsequent steps at a Health Care Ethics Committee meeting:

1. Determine the clinical and psychosocial facts of the case
    a. the patient's diagnosis and problem list
    b. the patient's prognosis
    c. the treatment options
    d. the health care institution's policies, practices, and regulations relevant to the case
    e. the way similar cases have been addressed in the past
2. Identify the key stakeholders' perspectives
    a. determine if any have been coerced
    b. determine the patient's values and preferences in the specific health care context
    c. clarify the legally appointed decision-makers' contributions
    d. organize the care team and conduct a discussion of the patient's situation
3. Formulate the bioethical issues and dilemmas
4. List the possible short- and long-term benefits and possible risks of harms for the patient

5. Work towards consensus through compromise, even if full consensus is not achieved
6. Develop a plan for implementation
    a. steps to be taken
    b. procedures to communicate advice, recommendations or decisions
    c. procedures to document the advice, recommendations or decisions (patient's medical record and chart)
7. Monitor the plan's impact on the patient and revise it if necessary
8. Evaluate the case review procedures
    a. list the procedures and policies in need of revision
    b. arrange to present the case as part of the continuing bioethics education of the staff
    c. ask the stakeholders to evaluate the review process
9. Develop an archive of case reviews to consult in the future

Appendix IV

RESEARCH ETHICS COMMITTEES PROTOCOL REVIEW FORM STANDARD OPERATING PROCEDURES FOR THE BIOETHICAL REVIEW OF A CLINICAL TRIAL

A partial checklist of subsequent steps at a Research Ethics Committee meeting:

1. The chairperson announces the presence of guests (though they are not permitted to participate in discussions or ask questions during the meeting).
2. The chairperson calls upon those members who were given the primary responsibility of reviewing the protocol to offer their remarks (all members should have received a copy of all the protocols to be discussed at the meeting well in advance of convening).
3. The members participate in the review process
    a. the scientific review
        i. the scientific design
        ii. the scientific hypotheses (if any)
        iii. the scientific methodology
        iv. the feasibility of the study
        v. statistical justification of the number of study participants (including controls)
    b. the regulatory/legal review (if necessary)
    c. the bioethical review
        i. the consent form is scrutinized
        ii. the study participants' well-being is discussed in detail

iii. the principal investigator potential conflicts of interests are determined
iv. the chairperson and members determine if the principal investigator needs to be invited to attend the meeting in order to clarify important aspects of the protocol – particularly the bioethical – design procedures that will be in place to protect the research participants

4. The chairperson calls upon the members to express their critical concerns
   a. clarification of technical scientific terms
   b. clarification of regulations particularly relevant to the protocol
   c. clarification of the bioethical design of the trial
   d. if revisions are necessary, the chairperson reads them aloud
5. Take action
   a. consensus is common, but if none emerges a vote is required
   b. the chairperson announces the result of the vote
6. Review previously unapproved protocols that were contingently approved.
7. Review previously tabled protocols.
8. Schedule the consideration of new procedures, policies, and regulations, dealing with such questions as 'Should new members be added to the Research Ethics Committee?' 'Should a "rule of procedure" be changed or repealed?' – each set of members (all scientists) have one vote. 'Should each member have one vote?'
9. The Committee's decision (to approve, to contingently approve based on specific revisions permitting resubmission, to table for subsequent Committee action,or to disapprove) is conveyed by the chairperson to the principal investigator.

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 Member 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).

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