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Report of the International Bioethics Committee of UNESCO (IBC) on Consent

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I. INTRODUCTION

1. When drawing up its reports on specific subjects⁽¹⁾, the International Bioethics Committee (IBC) touched on the issue of consent. However, at its twelfth session (Tokyo, Japan, 15-17 December 2005), the Committee considered that although consent is a traditional issue of bioethics, further discussion and reflection was needed in the light of advances in science and technology and the cultural specificities of each society. The Committee therefore decided to set up a working group to focus on the principle of consent as set forth in the Universal Declaration on Bioethics and Human Rights (2005).

2. Adopted by acclamation on 19 October 2005 by the 33rd General Conference of UNESCO, the **Universal Declaration on Bioethics and Human Rights** (hereafter “the Declaration”) devotes two articles to the issue of consent: Article 6⁽²⁾ addresses the principle of consent and Article 7⁽³⁾ covers the case of persons without the capacity to consent.

3. Aware of the difficulties that the practical application of the principle of consent may be faced with, by the present report IBC wishes to enlighten States, organizations and citizens and support the actions they have undertaken or intend to undertake, so that the consent of a person “for any medical intervention (...) or scientific research” be the expression of his/her freedom.

4. This report should not be considered as neither exhaustive nor prescriptive. It lies within a context where the principle of consent has been, and continues to be, the subject of intense debate at both international and local levels. It should also be recalled that the principle of consent has already been dealt with in existing international standard-setting instruments within and outside the framework of the United Nations system (more information is provided in Appendix 1 of this report). Whilst this report focuses on Articles 6 and 7 of the Declaration which address the issue of consent, these articles shall not be considered and interpreted separately from the other articles of the Declaration. As stated in Article 26, all principles “are to be understood as complementary and interrelated” and “considered in the context of the other principles, as appropriate and relevant in the circumstances”. Moreover, although this report addresses the difficulties that the application of Articles 6 and 7 of the Declaration may be faced with, it should be recalled that any limitation to their application should be by law, consistent with international human rights law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others (as stated in Article 27 of the Declaration).

1. Human gene therapy (Report of 1994, Ref.: SHS-94/CONF.011/8), genetic screening and testing (Report of 1994, Ref.: SHS-94/CONF.011/7), genetic counselling (Report of 1995, Ref.: CIP/BIO/95/CONF.002/4), ethics and neurosciences (Report of 1995, Ref.: CIP/BIO/95/CONF.002/3), bioethics and human population genetics research (Report of 1995, Ref.: CIP/BIO/95/CONF.002/5), access to experimental treatment and experimentation on human subjects (Report of 1996, Ref.: CIP/BIO.501/96/4), confidentiality and genetic data (Report of 2000, Ref.: BIO-503/99/CIB-6/GT-2/3), use of embryonic stem cells in therapeutic research (Report of 2001, Ref.: BIO-7/00/GT-1/2 (Rev. 3)), human genetic data (Report of 2002, Ref.: SHS-503/01/CIB-8/3 (Rev.2)), pre-implantation genetic diagnosis (Report of 2003, Ref.: SHS-EST/02/CIB-9/2 (Rev. 3)).

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

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

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

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

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

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

II. GENERAL FRAMEWORK

5. Informed consent is a fundamental principle that has marked the emergence of modern medical ethics based on personal autonomy. The need for informed consent in biomedical research was emphasized by the Nuremberg trials that revealed inhuman experimentation on prisoners in concentration camps. Its importance in the context of scientific research was further strengthened by many examples of unethical human research continued even in the post World War II period. In the clinical context, the importance of informed consent has been recognized as a consequence of the rising patients' rights movement and emerging biomedical technologies that emphasized the necessity to decide about the complex health-care choices to be made by the patient him/herself. The introduction of the practice of informed consent has also transformed a traditional paternalistic health-care professional-patient relationship.

6. Consent of a person constitutes one of the fundamental principles that practices must comply with in the field of application of the Universal Declaration on Bioethics and Human Rights. The principle of consent is closely related to the principle of autonomy (Art. 5 of the Declaration) and the affirmation of human rights and respect for human dignity (Art. 3 of the Declaration). The very structure of the text of the Declaration clearly reflects this close link.

7. Autonomy implies responsibility. The power to decide for one's self entails *ipso facto* that one accepts the consequences of one's actions, which, in health matters, can be awesome. Therefore, it should be emphasized that the person needs to be informed of the precise consequences of his/her choice, and this in turn leads one to wonder about the conditions under which consent is "informed" and obtained.

8. Respect for the autonomy of persons to make decisions, while taking responsibility for those decisions, is closely related to the fundamental Article 1 of the Universal Declaration of Human Rights 1948 which holds that all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

9. How, therefore, can this affirmation, which is also an extension of Article 3 on "Human dignity and human rights" of the Declaration, be contested? Nevertheless, the scope should not be underestimated. The close connection between autonomy and responsibility supposes that the consent be freely given by the person concerned, that the clearest possible information be provided, that his/her faculties of comprehension be intact, that he/she has been able to measure the consequences of the illness and its progress, and that he/she comprehends the advantages and disadvantages of possible alternative treatment.

10. A principle cannot simply be affirmed without examining the conditions of its implementation and the consequences of its application: such is the aim of this chapter. The following topics will be dealt with:

- the content of the information,
- the conditions of obtaining consent,
- the manner of expressing consent,
- specific difficulties in the application of the principle of consent.

II.1 The content of the information

11. Article 6 of the Declaration states that "informed" consent is to be "based on adequate information". As a general rule, an individual has to receive comprehensible, relevant, structured and individually tailored information that makes it possible for that individual to make a decision on whether or not to accept medical intervention or to participate in scientific research. But it is still necessary to specify what is understood by that.

12. With regard to the consent of the patient with a view to medical intervention, some important elements should be taken into account:

- the diagnosis and the prognosis;
- the nature and the process of the intervention;
- the expected benefits of the intervention;
- the possible undesirable side effects of the intervention;
- possibilities, benefits and risks of alternative interventions.

Other elements that also need to be taken into account concern the experience and capabilities of the professionals involved in the medical intervention and their possible financial benefit.

13. In the case of scientific research, it is necessary to make the person aware of the aim of the research, the methodology and the duration, expected benefits for him/her or for other persons concerned and the risks involved.

14. When consent is not given, it should never lead to less diligent care of the patient nor to any kind of discrimination. The same holds true for research: persons refusing to participate should never be put at a disadvantage because of their decision and should continue to benefit from all standard care their condition requires.

15. And finally, in accordance with the Declaration, the person should be informed that consent may be withdrawn at any time and for any reason, both in any preventive, diagnostic and therapeutic medical intervention and in scientific research, without any disadvantage or prejudice.

II.2 Conditions of obtaining consent

16. It is the duty of the person carrying out the medical intervention or the scientific research to obtain informed consent beforehand.

17. Although the doctor-patient relationship cannot be symmetrical, it nevertheless presumes mutual confidence and respect of confidentiality. A collaborative relationship, rather than a paternalistic relationship, should therefore be encouraged.

18. For the doctor, providing a patient with information should not be merely an administrative procedure or a legal obligation, but rather an acknowledgement of the trust placed in him/her by the patient. Information needs to be adapted according to the patient and his/her degree of tolerance: for example, when a serious illness is disclosed, tact and choice of words are particularly important.

19. Setting out the risks that a course of treatment or research may involve is a delicate procedure. In certain countries, in the case of a medical accident, jurisprudence convicts the doctor who has not mentioned the exceptional risks that certain clinical practices entail. But an exhaustive list of the major risks could cause the person concerned to be unduly fearful and it is necessary to involve the patient in the knowledge of his/her disease and avoid causing emotional trauma. Besides, some patients do not want to be informed before giving their consent and put themselves completely in the hands of their doctor.

20. In obtaining informed consent, the patient or a participant in a proposed research may face doubts about the understanding of the objectives, risks, benefits and expected results of the proposal from the physician or investigator, or even about his/her rights. In such cases a mediator may be called upon to analyze the information given to the patient or the possible participant (that must be free of dogmatism and coercion) and render the consent more comprehensible.

II.3 The manner of expressing consent

21. Consent should be 'express', i.e. leaving no doubt as to the will of the person concerned. It may be expressed in writing, orally or even by gesture according to circumstances and cultures.

22. Different perceptions of expressing consent exist according to different regions of the world. In fact, whilst in many countries written consent is considered as offering maximum guarantee, some societies practise oral consent, to the extent that to ask for written confirmation of a commitment is an indication of mistrust and uncertainty and offends the person concerned.

23. One specific way of expressing consent is through the use of advance directives. Advance directives have been increasingly considered as a means to express the autonomy of the person with regard to decisions on his/her health if he/she becomes unable to give valid consent because of incompetence (confused or unconscious patients). They contain, among others, instructions concerning medical or non-medical treatments or interventions the person requests or refuses.

24. There are two major types of advance directives: (1) instruction directives related to defined situations and (2) 'proxy' directives with the designation of a 'representative' entitled to take decisions in the name of the patient unable to consent (surrogate decision-maker). Both types are preferably associated to best cover the variety of possible needs or situations encountered.

25. Advance and 'proxy' directives apply to all medical situations, including problems related to the end of life and the numerous cases dealing with persons whose capacity of judgment is deteriorated, rendering them unable to express informed consent.

26. Advance directives have to be expressed by a person able to consent without any constraints from family or environment. They should be valid for a defined period (usually 3-5 years) and can be revoked or modified at will and at any time by the person.

27. Regulations and procedures dealing with advance directives and surrogate representative with respect to health and end-of-life care are subject to rapid evolution and considerable debate. In some countries, such directives are not required to follow specific conditions of form; as with other wills, they do not need to be established in an official document; further, to the extent that credible witnesses can attest their existence, they shall be taken into account even if they are not in writing. However, in other countries, by law, advance directives and/or designation of a surrogate representative have to be in writing in an official document.

28. In the follow-up of a chronic disease and within the framework of a longstanding therapeutic relationship, there is usually no point in requesting formally repeated consents, as long as the patient goes along with the investigations and treatment. If new methods appear (drugs, surgical possibilities), then it is necessary to update the information given earlier and to ask whether it changes anything in terms of consent.

29. What is said above doesn't mean that one should not present relevant information to the patient several times, and thus make sure that his/her consent is still valid. It should be recalled here that often the patient doesn't understand all of what is said, or all correctly, the first time the practitioner provides information. Thus, it is often advisable and even necessary to give the same information again, maybe under another form, later on.

II.4 Withdrawal of consent

30. Consent is valid as long as it has not been freely withdrawn, and as long as the information that the consent has been based on remains correct. Consent may be withdrawn at any time. The patient is autonomous and decides on what appears to him/her to be the best course of action or non-action.

31. Should a patient withdraw his/her consent, the correct practice, in the spirit of the Declaration, is to expose clearly and serenely the possible consequences of such withdrawal, making sure that they are understood by the patient – who assumes the ultimate responsibility.

III. CIRCUMSTANCES OF APPLICATION

III.1 Consent in various categories of practices

32. Article 6 of the Declaration makes a distinction between preventive, diagnostic and therapeutic medical intervention (paragraph 1) and scientific research (paragraph 2). Paragraph 1) requires prior, free and informed consent from the persons concerned. It also states that consent should be express where appropriate. As far as scientific research is concerned, according to paragraph 2), consent of the person involved is always required to be prior, free, express and informed. Paragraph 3) introduces the notion of collective agreement and states that in appropriate cases, additional agreement of the legal representatives of the group or community may be sought. However, 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.

III.1.1. Clinical practice

33. In the clinical context, the characteristics of obtaining consent will depend on:
- the duration and the quality of the relationship between the provider and the recipient of health care,
 - the invasive character of the procedure,
 - the potential benefits and possible side-effects,
 - the possible impact for third parties, in particular family members,
 - the economic consequences, especially when the related cost is not or not entirely covered by a health insurance mechanism.

As indicated above, it is worth underlining that requesting and obtaining consent is not a one-time affair but that it is often a process where discussion with the patient is needed at several succeeding points in time, through an ongoing dialogue.

34. It should be underlined that, in general, adequate information given to the patient is the condition *sine qua non* for consent to be validly obtained; without adequate information, there can be no validly-given consent. One should emphasize that it is a systematic duty of the professional to give information which is complete and comprehensible. In this respect, the notion of *therapeutic privilege* (of the care professional) which appears in certain deontological codes cannot be supported anymore. There may sometimes be a place for a therapeutic *exception*: leading in exceptional circumstances to limiting or delaying the transmission of some information to the patient. Nevertheless, the rule is that information is provided in a comprehensive form and as soon as it is available. Regarding content and other aspects of information, some refer to the *reasonable person standard*. In any case however, the health-care professional has the responsibility to ensure that sufficient efforts have been made to inform the patient.

35. As clinical practice includes only situations of major health problems, invasive procedures or negative prognosis, various ways of obtaining consent are acceptable, according to different cases. One may in this regard consider local circumstances and socio-cultural features, while holding fast to the principles of bioethics as set forth in the Declaration and to the rules of medical/health law.

Clinical examples: Taking of blood

- Routine examinations in the follow-up of an anticoagulation therapy: appropriate explanation and consent are required at the beginning of the treatment; afterwards – barring special circumstances – no express consent need be obtained. The fact that the patient does not object to blood taking can be considered as the sign that he/her understands and agrees.
- Blood tests during a first visit: the physician has to provide sufficiently precise information on the analyses he intends to ask for in order to assess the health condition of the patient. The degree of information may legitimately vary, e.g.: “These three tests will check on the condition of your liver”, or “I propose to have a battery of tests which are usually recommended in the check-up of a person of your age, in relation to the condition of the following organs: ...”. But more precise indications are required in situations where, for various reasons, express consent is called for (see below).
- HIV test: the practical and symbolic weight/importance of this test is well known. It requires in every circumstance an express consent to be tested (which might be oral – the practitioner may judge if a written consent is called for).
- Genetic testing: thorough information about the test(s) and the possible findings and consequences is imperative, as the results are likely to have an impact, not only on the person tested but on related ones (children and potential children, possibly siblings – as well as a *fiancé*/engaged partner, if carried out in view of a marriage).
- Blood donation: the situation is different here: blood donations have to go through an extensive array of tests nowadays in order to prevent any risks for the recipients. The donor gives blood under totally free and voluntary circumstances but can do so only if he/she accepts without restriction that the required tests be performed. There is no possibility of saying: “I want to donate my blood but on the condition that such and such a test will not be carried out”.

Primary medical care

36. There are a number of routine, simple non-invasive interventions in daily medical practice the nature of which can be assumed to be known by the ordinary patient: e.g. measuring blood pressure. Medical physical examination (palpation or passive movement) of a body part which hurts or is the object of other complaints might also be undertaken without requiring an express consent. When the doctor says “I am going to examine your knee – or your abdomen”, the fact that the patient shows no opposition can be considered a tacit agreement. Quite different is the situation in which a health-care professional would perform a gynaecological examination in a patient who came for an ear complaint. Then, precise information on the need for this additional examination must be given and express consent obtained. In such a situation; prior, free and informed consent should be given, though it might not be necessarily written.

37. Further, a great deal of primary care, especially in countries with an aging population, is related to chronic diseases, including repeated (routine) consultations/visits by the patient. In such conditions, one would not require that the provider inform each time on practically unchanged features of the patient’s condition and treatment.

Invasive medical interventions

38. The more invasive the intervention is and the more severe physical, psychological and/or socio-economic its consequences are, the more express and formalized the consent will need to be. Examples: surgery with losses that are practically or symbolically severe (mastectomy, possible loss of sexual potency, anus praeternaturalis, limb amputations, etc.), hazardous surgery on the spine – with possible paralytic sequelae, heavy cancer treatment with a serious loss of quality of life for months (it should be compared with the potential quality of life and length of survival without such heavy therapy). The same is true for evident reasons for surgical sterilization or termination of pregnancy; as well as for medically assisted procreation. It is advisable in such cases to give the patient a certain time to think the question over.

39. It is prudent to ask for a written consent in a number of other situations such as those mentioned in the paragraph above. It is routinely requested before medical interventions which are of an optional, non-indispensable nature; for example aesthetic surgery, where the quality of the result might well be appreciated differently by different persons, and the methods being currently developed under the denomination of enhancement medicine.

III.1.2. Biomedical and clinical research

40. What is stated in the previous paragraph on clinical practice also applies in the case of in the research. The issue of consent and the practical circumstances of obtaining it vary according to additional criteria, in particular:

- whether the research is on healthy volunteers,
- whether or not patients taking part in a research are likely to benefit from it directly or indirectly.

There are several other aspects to be considered, in relation to the civil status and ability to judge/consent of the participants in research (minors, persons without the capacity to consent, etc). They are treated in a following section of this document.

41. Generally, diligent care should be taken to ensure that research participants are not under pressure to participate. Thus, as a general rule, one should refrain from requesting prisoners, military personnel or others in a dependent situation, to be involved in such research.

42. In dealing with *health volunteers*, the significant fact is that those persons have not, in the first place, requested care/involvement in a medical procedure. They agree to be part of research, either for altruistic reasons or to seek compensation in some other way. The risks involved in the research should be minimized. A description of the research procedures, known risks, uncertainties and participant responsibilities should be provided in order to achieve informed consent. Undue incentives should not be offered to participants and adequate insurance covering adverse events and outcomes should be provided. Participation should be described in precise terms in writing and written informed consent should be mandatory.

43. Because of the recent tendency, within Europe for example, to involve healthy volunteers coming from other countries as tourists for a limited period, and in order to avoid possible undesirable consequences, several countries have established registers to follow the frequency with which a volunteer is involved/'employed'. These registers may help to avoid possible dependency because of the profit involved.

44. Regarding research with *patients for whom there is no foreseen benefit*, the situation is somewhat akin to what was just said for healthy volunteers: the risks should be reasonable and provisions should be made to avoid any damage they might suffer from the research or, as might happen, to alleviate or compensate any such damage.

45. For *patients who might benefit from the research*, the possible risks linked to the project – which should always be as limited as possible – have to be considered in relation to the severity of the patient's condition and to the chances of a significant improvement. Desperate situations allow riskier procedures than research in situations that do not represent a threat to life or to major functions.

46. A key ethical principle of research with human subjects is that if studies can be undertaken with scientific validity on persons who can provide their own informed and free consent, they should not be carried out on persons unable to consent, except when there is a likelihood that the project is will bring them direct benefit or when no comparable study can be undertaken – and relevant results obtained – with other patients. The same caution applies if prospective research participants appear particularly vulnerable. The right to cease participation in a research project is also guaranteed without prejudice to the person who should continue to benefit from all standard care his/her condition requires.

III.1.3. Epidemiological research

47. The objective of epidemiological research is to elucidate the characteristics in a population of the prevalence and incidence of a disease or other health problem (accidents, violence, intoxications...) and of the distribution of the problem (e.g. according to age, sex, type of work, social conditions, place of residence, daily habits/behaviour).

48. It might include a variety of modes of participation, such as:

- use of already collected data (in a medical, sociological or other investigation, possibly coded or anonymized);
- filling out a written or electronic questionnaire;
- participating in an interview;
- providing samples of biological matter (blood, urine, saliva etc.);

49. Understandable and sufficient prior information provided to the person is of course a requirement. With regard to consent, the fact of freely filling out a questionnaire or participating in an interview is a clear indication of consent, but participants in research should be completely informed about the use made of the data they provide, including how and when this data might be coded or anonymized, and about their right to quit the project at any time.

50. For biological samples, their potential use and its limits should be clearly defined. Whether it is possible or not to trace a result back to the participant/informer is a significant ethical issue. Participants should be informed of the advantages and disadvantages of anonymization and whether or not the researcher will report relevant results to participants. In any event, in epidemiological studies that include genetic data from biologic samples, informed consent should comply with the provisions of the UNESCO Universal Declaration on Human Genome and Human Rights and the International Declaration on Human Genetic Data.

51. Close attention should be given to the interests of third parties, in particular in epidemiological research using genetic data and in socio-anthropological studies.

52. The involvement in research of many members of a given community raises specific questions (to which article 6 (3) of the Declaration refers). This is of great interest for studies about genetic predispositions to certain diseases. A desired collective agreement should be sought in a socially accepted, democratic, fashion. But it should always remain possible for individuals to refuse to collaborate and any exertion of pressure should be avoided if they refuse to join such a programme or withdraw from it.

Data collected for one study used for other studies

53. The principle of informed consent demands that the person is adequately informed about the use made of the data/material he/she provides. There are however situations where opportunities to use already collected data/material for another research only appear later on. From a scientific point of view, one would wish not to forego such a possibility and the consent issue here is a delicate one. Whenever possible, one may go to the participants and ask for their consent for the new line of study. For situations where this is not practicable, countries, ethical review boards or professional societies should establish specific regulations, including examination by expert bodies, to waive the individual consent requirement. In addition, individuals should have a right to withdraw from the research project or be entitled in some way to protect their rights. Also, another chance of obtaining consent should be given when research progress creates a different situation as to the likely – beneficial – outcome. The need to update the information given earlier applies in this context as well.

54. Consent should be based on the actual purpose of the epidemiological research project concerned. It is not acceptable to ask participants in a research project to give an *overall prior consent* (so-called “blanc consent”) to the effect that they would agree to any study that can be carried out with the data/material they provided, unless the data/material be irretrievably unlinked to the participants.

III.1.4. Public health

55. First, it should be noted that epidemiological research is often of public health importance. What has been said above applies.

56. The major issue here is the fact that public health measures, aiming at preventing, eradicating or alleviating a problem of importance for the whole population – or groups within it, might interfere with the self-determination of individuals. Such restrictions on the freedom of people to choose for themselves should be strictly regulated and be in accordance with Article 27 of the Declaration on “Limitations on the application of the principles”. For example, the threat of an epidemic legitimates the public hand to order compulsory measures; a well-known example is the *quarantine*, enforced since the XIVth century in Europe to try to limit the spread of the plague (Black Death). Today, such threats may lead to ordering the immunization of an entire population or categories within it (e.g., persons employed in the health field). Furthermore, even without immediate epidemic danger, it might be justified to declare immunizations compulsory in order to ensure a sufficient coverage in the population.

57. Around 2005-2006, countries made plans concerning avian influenza and the major danger it would represent in case of a mutation allowing the disease to pass from human to human. In an epidemic, the right to freely choose one’s physician or hospital might well be suspended and patients directed to a place of treatment according to an established plan (that would also be an exception to the required informed consent of the individual). In fact, it is clear that health and hospital planning for a country or region, meaning concentrating technological resources in certain points rather than in others, also induces, *per se*, limits to the possible choices by the persons. Such constraints however are usually understood by the public and might be established by law.

58. The World Health Organization (WHO) has been working, with others, on the range of challenging ethical issues raised by a potential influenza pandemic, to provide Member States with comprehensive, practical guidance on how to incorporate ethical (and related human rights and legal) considerations into their plans and preparation for, and response to, pandemic influenza⁽⁴⁾.

59. Similar issues are raised by other public health measures which benefit the population as a whole and are sometimes imposed. For example in some countries, for decades salt has been iodized in order to prevent hypothyroidism and goitre (with very good results): people who did not want to ingest iodine with salt had no choice (today however, it is possible to buy iodine-free salt).

60. In occupational medicine compulsory periodic controls, a part of public health, are prescribed in jobs involving serious risks. From the perspective of public health, this is justifiable. However, in terms of consent the worker may have no choice but to accept the controls if he/she wishes to keep his/her job.

61. Because individual behaviour may have public health consequences, medical intervention may be justified without consent in specific cases in order to protect individuals.

62. The issue of compulsory examination or treatment of an individual to protect the health of others is a debated issue. In the case where a potentially severe disease could be passed on in daily life circumstances and unknowingly, e.g. in public transport or areas, obligatory, *ex officio*, measures might be justified. Regarding communicable diseases, e.g. sexually transmitted diseases, in which there is little or no danger of a large scale epidemic and where one might consider that persons at risk (sexual contacts) act freely and usually have adequate information about possible threats to their health, some consider it logical nevertheless to trace contacts and examine/treat them even without their consent. In other parts of the world it is now viewed as an undue infringement on the individual’s autonomy.

4. WHO guidelines for investigation of human cases of avian influenza A(H5N1), January 2007.

63. A situation in which compulsory treatment is permitted in some legal systems is drug addiction. The results of such measures however are very disappointing: without their full consent and personal commitment it proves quite difficult to help persons to quit the habit. A related issue is the one of the pregnant woman who goes on using drugs at the end of a pregnancy and thus harms her child. Some States in the United States of America permit courts to order a compulsory caesarean section against the will of the woman; such a decision cannot be made in Western European legal systems, which consider that it is too large an infringement on the autonomy of the mother, while the benefit for the child is also disputed.

64. There are discussions about the possibility of castrating persons with severe sexual perversions which prove not be controlled by any treatment. It has been suggested as the only procedure that would permit such persons to be released from prison – or other confinement – without continuing to be dangerous. It is difficult to weigh whether this should be allowed, even if the individual requests it. And it is certainly unacceptable if he refuses, as it represents a most important damage to physical integrity.

III.1.5. Emergency situations

65. Emergency situations pose specific questions because of the need to act rapidly to save the patient's life and/or limit consequences to the maximum possible extent. This represents evident constraints in terms of obtaining the prior and fully informed consent of the person. In addition, the patient might be confused or, worse, in an unconscious condition and thus cannot give a valid determination.

66. One has then to deal with two issues:

- the determination by a legal representative. The question of who can be a legitimate representative, as different from a legal one, has to be addressed and depends significantly on socio-cultural features (see elsewhere in this report). In some legislations, the person may designate a so-called *therapeutic representative* who does not need to be the legal representative;
- the duty of the health practitioner to provide care, prolong life, alleviate suffering. This entails particular difficulties when the practitioner considers that the proxy decision is not in the best interest of the patient.

67. According to the principle of patient autonomy, the personal conviction of the health professional should not override a known valid prior determination of the patient.

68. In life-threatening situations where there is no known or likely preference of the patient and where an appropriate representative is not available or gives an unclear determination, several ethical codes emphasize the duty to save the life of the patient as much as medically reasonable.

69. It is necessary here to underline the relevance of advance directives (also called *living wills*) issued by the patient, making clear what kind of treatment he/she wishes – or doesn't wish – in particular cases (see par. 21 to 29). Until recently, physicians often considered that such directives were useful documents that they could refer to, but that they were under no duty to follow. Today it is more and more generally acknowledged that advance directives are binding for the health-care professionals, who could act against them only for stringent, imperative, reasons. In several legal systems, this is already part of health law.

70. In situations where there are no advance directives nor legal representative, the health-care professionals have a duty to obtain the opinion of the person's relatives and/or close friends about his/her preferences – while remaining aware of possible conflicts of interest between them and the patient. If in doubt, the decision would lean towards measures most likely to save the patient and limit the adverse consequences (see above). In case of opposition between the professional and the family/friends, and assuming that some delay is tolerable, some legal systems require the decision of a civil judiciary authority or court. In

any event, it is recommended that steps be taken by States to establish a legal framework to deal with such situation.

71. As soon as the person concerned is once again in a position to decide, he/she should be fully informed of the situation and of the medical measures undertaken while he/she could not be aware of them, and his/her consent should be obtained before going further with the treatment.

72. Research projects in emergency situations pose comparable questions. They should be looked at in considering what has just been said as well as what appears above about clinical/biomedical research (see section III.1.2, par. 46), and what will be said about research on subjects not able

to consent (see section III.2.2). Clinical studies in unconscious patients for whom neither a family member or close friend nor an advance directive is available are highly controversial among clinicians and ethicists and are dealt with differently in different countries.

II.1.6. Organ, tissue and cell donation

73. Cadaver donors are the most common donors in the western hemisphere, though the situation is evolving, in particular with regard to kidney transplantation. If permission was given by the subject before death, utilization of the body is ethically acceptable. Nevertheless, there can be problems in the practice of using the body of the deceased. In some cultures the relatives retain rights over the body of the deceased by virtue of the blood links and/or affection that previously bound them.

74. There are two main types of legislation concerning consent to organ, tissue and cell donation from cadavers:

- a) presumed consent: it is based on the view that every deceased person is a potential donor, except when in life the subject expressly stated the opposite. It is believed this legislation would significantly increase the availability of organs, tissues and cells for transplantation;
- b) express consent: it requires the explicit authorization by the subject or, after his death, by the relatives. In some countries the authorization must be in writing and notarized.

In certain countries it is indeed admitted in the legal systems that the family has the right to make decisions concerning the body of the deceased.

Case: Jehovah Witnesses

The case of the Jehovah Witnesses is one that has been much debated in recent decades. Because of their religious conviction, the Jehovah Witnesses absolutely refuse to receive blood transfusions. This stance implies severe risks, which might be vital, in case of severe haemorrhage. It is then a major ethical question to know whether one should overrule the refusal of the competent adult patient and nevertheless give him/her the transfusions, which might be life-saving.

In the past, at a time when medical practice was marked by professional paternalism, it wasn't rare that medical teams would simply disregard the patient's expressed position and transfuse nevertheless. Following on recent evolution, particularly in North America, things have largely changed. Care professionals realized that they might well save the patient's life through transfusions but, doing this, might make them pariahs, outcasts, in their own social group which would reject them because they received blood. Such a result of acting on the conviction that one knows better than the patient what is good for him/her must be questioned – even though it is delicate, to say the least, to leave a young mother die postpartum because of uncontrollable bleeding, for example. Yet, the usually prevalent position and practice today is to pay heed to those refusals and refrain from transfusing (it is to be noted here that intensive medicine nowadays has at its disposal a number of non-blood solutions and measures which may avoid a tragic outcome – and Jehovah Witnesses members are quite well informed in this regard).

In such situations, the teenager should in principle be considered as an adult. The issue is more difficult when an infant or young child is concerned. On the basis of the general protection duty of the State, in an emergency one might then make the relevant Public Office the guardian of the child, giving back their rights to the parents when the child's life is no longer in danger. Although such a position appears understandable, it is not accepted by all today: its unfortunate consequence might also be that the child is later rejected by his/her family and community.

75. For living donors, the usual principles in respect to the adult able to consent hold true. In principle, the conditions for obtaining consent can be more adequately fulfilled in the case of living donation than of post-mortem donation (because of the possibility of interaction with the donor). In practice, however, the autonomy of the living donor can be compromised. Special care should be taken to guarantee that: (a) the donor is fully informed of the possible adverse effects and long-term consequences of the donation; (b) emotional pressures have not compromised the free consent of the donor; and (c) consent is given without inducement by financial or other personal gain.

III.2 Consent in various categories of subjects requiring special protection

76. Article 7 of the Declaration stipulates that special protection is to be given to persons who do not have the capacity to consent to research or medical practice. A person not able to consent may be a minor, a mentally disabled or legally incapacitated adult, either for a given period or permanently. The protection shall be given by domestic law and the best interest of the person as well as his/her participation in the decision-making process should be sought. In the case of research, the Declaration establishes the general principle that such research may only be carried out if it is of direct benefit to the health of the person concerned, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Exceptionally, it stipulates that research that is not expected to be of direct benefit to the health of the person concerned may only be carried out with the utmost restraint, taking care to expose the person to minimal risk and minimal burden and in the interests of persons in the same category.

77. Autonomy is often defined as self rule and refers to the right of persons to make authentic choices about what they shall do, what shall be done to them and, as far as is possible, what should happen to them. However there are numerous sets of circumstances where the capacity to exercise autonomy is subject to limits without calling respect for autonomy into question. These are examined in the following sections.

III.2.1. Lack of capacity to consent

78. Persons without the capacity to consent can be identified as those who, for reasons internal to themselves, do not have the capacity to make autonomous choices irrespective of their external circumstances. Various groups of people have been traditionally labelled in this way. They include people with learning difficulties, the mentally ill, children, confused elderly and unconscious people.

79. The criteria for the capacity to consent have included the ability to understand the issues involved in the decisions at stake, the ability to evaluate these rationally, a reasonable outcome of the decision and evidence of a decision being made.

80. The general safeguard of the freedom of patients in these situations is that no judgment of capacity to consent should be called for unless there is evidence to undermine the normal assumption that people are able to decide for themselves. In other words, proof of incapacity is required not proof of capacity. Foolish decisions can be voluntarily made by the most autonomous people and the freedom to do so should not be restricted by imposing over-stringent standards of capacity.

81. While these look like objective criteria there are difficulties in their application. Inevitably the assessment by any judge of a person's capacity to consent is made from that judge's perspective of what it is to be understood, of what is rational and of what a reasonable outcome would look like. But there might be disagreement about each of these.

- i) For example the second criterion cannot discriminate definitively between patients who might be risk-takers in life and clinicians who are cautious. What appears to be rational to the former might not appear rational to the latter.

ii) People might also disagree about what constitutes a reasonable outcome to a decision. Here there is a danger of informed consent procedures – set up to ensure respect for autonomous decision-making – being rendered meaningless if the patient does not choose the outcome preferred by the clinician. For example, a patient might not wish to receive possible life-saving treatment for a malignant disease but rather maximise the quality of their remaining days by avoiding the rigours of cytotoxic medication. To interpret such an outcome as unreasonable would compromise the consent process for if the patient chooses the treatment he/she will be regarded as able to consent and so undergo the procedure and if he refuses then the procedure will still be carried out as the unreasonable choice will indicate his/her incapacity to consent and thus invalidate his/her refusal.

iii) Assessing the degree of understanding of data offered to a patient is not an exact science either. In accepting that a decision maker understands a situation, some people demand a more detailed grasp of a wider range of facts than others. To set the standard too high threatens to undermine the freedoms of patients when judged by their medically expert clinicians.

III.2.2. Groups of persons without the capacity to consent

Neonates

82. It is impossible for neonates to make decisions, to understand information, to process information rationally or to desire reasonable outcomes. In other words they can satisfy none of the standard criteria of capacity of consent. Yet decisions have to be made for them. The best candidates for this role are the parents, on the assumption that of all people, it is they who will have the best interests of their child at heart.

83. Sadly, in some cases parents do not make decisions in the best interests of their children. This is problematic in health-care settings, especially when the results of the decisions could be very damaging to the health of the child. In most societies provision is made to protect children whose parents are not capable of, or willing to provide the necessities of life for their offspring. In those cases it is possible for the state to step in and remove the decision-making role from them. This is done by making the child a ward of the court and placing that role in responsible hands. This step should be one of last resort as it usually has serious negative repercussions in the relationship between the health professional and the parents. Such an outcome jeopardizes the future welfare of the child who is less likely in future to be presented for health-care surveillance and care at appropriate times.

Children

84. Likewise, it might appear that all children, by their very nature, are unable to consent because they cannot think like adults. Whilst this is certainly true of very young children, as children develop they show marked differences from each other. Fixing a chronological age such as 16 years to mark the attainment of competence is unsafe. The United Nations Convention on the Rights of the Child asserts that children have the right to say what they think should happen when adults make decisions that affect them and to have their opinions taken into account (Article 12), have the right to get and share information (Article 13), have the right to think and believe what they want and practice their religion as long as they do not stop other people enjoying their rights (Article 14), and have the right to privacy (Article 16). All these assume growing levels of capacity to consent which have to be taken seriously.

85. But when will they be capable of making their own decisions? The idea that they will attain a magical common age when this occurs was tested in the courts in the United Kingdom in the Gillick case (Gillick versus West Norfolk and Wisbech Health Authority & DHSS). In that case Mrs Gillick, a mother of teenage daughters, objected to the proposal to make contraceptive advice available to young women without the knowledge of their parents. She challenged the proposal in court and won. However the matter went to appeal and the decision of the lower court was overturned. In the celebrated judgment made by the Appeal Court the point about the different rates of maturity attained by young people at given ages was considered. The recommendation was that an arbitrary chronological age should be replaced by a test of maturity of the child to understand the nature of the decision to be made and the consequences likely to follow from the selection of the available options. Such a standard has been widely adopted in other countries since the judgment was made. Of course this places an additional burden on the health professional involved in seeking to offer a clinical intervention or advice. However this is seen as essential in order to safeguard the rights of the child mentioned above.

86. Clearly some decisions are easier to make than others insofar as they are more readily understood and the consequences of a poor choice are less onerous or dangerous.

One might properly apply some higher test of competence for decisions of greater moment. But here it is important to be cautious because it may undermine the rights of mature children to make their own decisions by setting the standards of maturity unacceptably high. Adults too are often able to make some kinds of decisions but not others and we might devise more stringent tests for the weighty decisions in their case. But the standards should be no higher in the case of children than it is in the case of such adults if we are to have proper regard for their autonomy.

87. Research activities involving children are carried out to learn more about the nature of paediatric development, disease and potential treatments. Though one might hope that it will in some cases be beneficial to the research participant, the activity cannot be said to be specifically designed for this purpose because of the nature of the research question. Here it differs from clinical treatment *per se*. As a result, parents cannot consent their children into research on the basis of the assumption that they are the ones who have the best interests of their child at heart, for the research procedures are not aimed specifically to ensure the best interests of their child. We do not know at this stage whether they are likely to be beneficial or not – indeed that is the research question being asked. Those who stand to benefit are future children for whom the results of the research will be valuable in informing their treatment.

Case: John

John was a small baby diagnosed as suffering from myeloid leukaemia. He was in a parlous state of health and the only possibility of rescue lay in a bone marrow transplant. But where could a matching donor be found in time? He was not an identical twin but his next best chance was to identify siblings who would be likely to provide the best candidate tissue. He had six siblings whose ages ranged from seventeen years to two and a half years. The first five were tested and though some of them would have provided good matches for others siblings none of them provided a good match for John. Finally his youngest brother was tested and found to be as near an ideal match as could be hoped for. The parents were desperate to see their baby's life saved and would give immediate consent. But they had a conflict of interest.

Whilst it was evidently in the interests of the recipient child for them to consent to the procedure it could not be said to be in the interest of the donor child. The clinicians therefore did not simply accede to their wishes but reflected on the case together with a class of medical students. It was concluded that despite the facts of the inexplicable, unpleasant and painful few days which the donor would experience in donating tissue the time would come when a mature view of it would be formed. The overwhelming chances were that he would be grateful to hear when old enough that he had been the means of saving his brother's life – or at least that he had been the means of giving a brother he was never to know the best possible chance of life. The consent was therefore called a *hypothetical consent*, that is, a consent which would likely be in accord with the feelings of the donor when mature. Such an outcome would, of course, be less likely if undue risks were taken with the donor's life such as the explantation of a whole organ. Given a carefully minimised level of risk, the child might also be grateful to learn that the use of his data, or his participation in a trial facilitated the discovery of a new treatment or increased understanding of a dreadful disease. Insofar as this is so then it might be said to approximate to an informed consent, albeit one which is anticipated, and thus constitute a show of respect for his surrogate autonomy.

88. But it is not acceptable to abandon this group, or indeed other specific groups of people who lack the ability to make their own choices to the suffering and consequences of diseases and conditions peculiar to them. Research into paediatric illness and child development, schizophrenia, degenerative neurological disease and so on is desperately needed.

89. In situation where there are no alternatives but to use members of these groups, one crucial safeguard required, to minimise loss of respect for autonomy in this connection, is the general rule which is applied to all groups of patients deemed to be unable to consent, viz. where the research into their various conditions can be carried out by employing autonomous participants then participants without the capacity to consent should not be used.

Clinically confused patients

90. There are a growing numbers of patients who once enjoyed the capacity to make decisions of all sorts in their lives but who, sadly, are no longer capable of doing so. Various forms of neurological deterioration including Alzheimer's disease rob people of such powers. How can we respect their compromised autonomy in making treatment decisions or other decisions which involve them in health related activities?

91. It would be unethical to take these patients any less seriously than fully competent patients. In approaching decisions concerning them we have much more to go on than we do in the case of neonates. These are people who have lived a full life, whose preferences, values and wishes are probably remembered by some, if not many, who knew them when well. Their offices should be sought when reflecting on what do to for the patient. They should not be asked to

Case: Susan

Susan was in her early fifties. Until just two years previously she had been a very active professional member of the community. A keen amateur opera singer, a senior science schoolmistress and a wonderful wife of a devoted husband. Then suddenly all began to change. Her memory began to fail and she began to repeat herself having forgotten that she had asked the same question but a few minutes before. Within months conversation became impossible, people were not recognized, ordinary activities were beyond her. She needed constant care for all her needs. Within six months of the onset of her illness she recognised nobody. Hospitalised, she seemed not even to respond to physical stimuli and her joints were rigid. She was painstakingly fed twice a day by her loved ones. At this stage the local medical school was developing a new curriculum and was seeking good cases. In neurology an Alzheimer's case was needed. Susan was identified as the ideal candidate. The family had wonderful recent home movies of her in full health and engaging in her favourite activities. What a graphic portrayal of the ravages of the disease would be provided by the juxtaposition of those images with a video recording of her daily care as currently provided. But how could such a video be made without her consent? How could her autonomy and dignity be respected were she to be involuntarily placed on permanent video record to be gazed upon by successive classes of young students? The case against the proposal seemed overwhelming until her husband came forward to offer the following account of Susan's life. She was an accomplished and enthusiastic teacher who was especially committed to medical education. When well she had been a tireless worker in the community, always putting others before herself. And now there was nothing she could do for learners or for society. Or was there? Yes, there was one last thing. She could be the means of helping young doctors understand something of the human tragedy and the clinical signs of Alzheimer's disease. "If she was given just one minute of lucidity and asked whether she would consent to the film", he said, "she would say 'Yes, Yes, Yes, please make the video recording. It is the last useful thing that I can do for humanity'. The curriculum committee was moved and convinced. The tape was made and has never failed to deeply impress the students. The circumstances of its making are shared with the class to demonstrate that the school teaches informed consent by both precept and example. The tape was shown at her funeral as a tribute. Here was no proxy consent from the husband but a substituted judgment enabling Susan to speak for herself – surely a mark of respect for her autonomy.

provide proxy consents but rather to help build a picture of the life of the patient in which to find the decision to be made. Insofar as it is possible to do this then it might be said that a substituted judgment about what the patient would consent to is being built.

Patients with learning difficulties

92. It is important not to confuse intellectual impairment with mental illness. This group of people represents a wide range of intellectual ability and no simple standard of capacity to consent can be assumed between them. In each case an assessment according to the criteria outlined above is called for in combination with an awareness of the nature of the decision to be made. Only in extremely serious cases will a person with this problem be unable to make a decision about anything. If it were possible to identify a life previous to the onset of this developmental condition this would allow to collect sufficient information to build substituted judgments. Likewise, there is no prospect of a growing intellectual maturity to anticipate in making a hypothetical judgment about what will be regarded by the person as an acceptable decision. Thus in those cases where either the impairment is so great that the decision is too onerous or complex to be grasped by the person we have to make a best interests judgment on their behalf.

Mentally ill patients

93. It has long been accepted and practiced that a psychiatric condition might be a reason to forego/waive the consent of the patient – who is not in a condition to be a judge of his/her best interest. It should be underlined however that it does not mean that the patient's expressed opinion should in no way be taken into account, that it can be neglected. The situation should be judged professionally, with nuance and proportionality and, to the largest extent possible, one should consider carefully what abilities the patient manifests. This holds true as well for other persons viewed as lacking capacity to consent.

94. As with intellectual impairment so too with mental illness, it cannot be assumed that all persons in the group are equally able to consent or otherwise. On the one extreme, people in a psychotic state cannot, by definition, make autonomous choices. On the other hand, when not in a florid state, a person with schizophrenia might be quite clear about how he/she feels about matters of life and how he/she would wish to address them. It is the same person being dealt with when he/she is ill and every endeavour must be made to carry the memory of him/her, when well, into the decision-making procedures on his/her behalf.

95. The capacity of consent of a mentally ill person must be assessed independently of the nature of the decision which he/she wishes to make. Despite reasonableness of outcome being a criterion of capacity, it is important to acknowledge the possibility of differences in what counts as reasonable between the patient and the clinician.

Case: C versus Broadmoor Hospital

C was a Jamaican immigrant to London soon after the Second World War. He attempted to murder his girlfriend and was sent to Brixton prison. On examination he was diagnosed as a paranoid schizophrenic and removed to Broadmoor Special Hospital. Thirty years later he was still subject to grand delusions and there was little or no prospect of his release. He developed a gangrenous foot and was given only a 15% chance of survival without amputation. The medical personnel recommended him for the procedure as being in his best interests. He refused to lose his leg. It might have been assumed that he had no capacity to make such a decision so the case went to court. The court decided that his decision had nothing to do with a failure to understand the prognosis, nor with his paranoia. Rather it took his assertion that 'I would rather be dead with two legs than alive with one' seriously and thought that he was perfectly clear about this. He kept his leg – and he survived. However the latter point was not a vindication of the court's decision for that had nothing to do with C's reason for refusing the surgery.

Unconscious patients

96. Decisions concerning treatment and research activities are often called for in the case of unconscious patients. Should doctors resuscitate? Should they use this or that medication in the early stages of cardiac arrest? These are questions intensive-care doctors deal with every day and clearly their patients are not capable of consenting to or refusing such treatments. Doctors sometimes have the kind of information referred to in the case of

substituted decisions to go on. Relatives are the usual source of this kind of information. On the other hand, as time is of the essence in these cases, doctors might not be able to conduct such enquiries and choose to err in opting for life. This can turn out to be a disaster for many survivors whose quality of life is dreadful. Is there any other way in which doctors can preserve respect for the autonomy of such patients?

97. Doctors might at times, and this is likely to become more frequent, have direct access to what seem to be the express wishes of the unconscious patient – advance directives or a living will. Whilst such documents may be valuable guides to respect the autonomy of the patient, they are far from perfect and have inherent weaknesses which the clinician has to take into account. They might be old, out of date and the patient's views might have changed if not repeated with time. Moreover, they are hypothetical wishes. They are of the form: 'if I am found to be in such-and-such a state I will regard that state as worse than death and not wish for any extraordinary means to be used to keep me alive'. However, it is often imagined that certain states are unacceptable but when they occur, they are in fact not so. It is also necessary to know under what circumstances the documents were produced and to be sure that the person was not under duress. Furthermore, in case of an urgent life-saving decision needing to be made, the caring doctor cannot take prior instructions as the final word without such circumstances being established. Thus, whilst he/she would be negligent not to consider the document he/she should not be bound by it.

III.3 Consent in various categories of contexts

98. In addition to the internal conditions referred to above there might be external constraints upon the decision-maker's freedom to choose. For example, the freedom to choose can only be constrained in rare sets of external circumstances each of which involves the protection of the autonomy of others. In some cases medical personnel can compulsorily detain mentally-ill persons for protection and treatment if they constitute a danger to the freedom and safety of others. Similarly, persons who suffer from a very serious infectious disease may be compulsorily removed from their place of abode or work in order to protect the health of others. Such restrictions on the freedom of people to choose for themselves are very few and are strictly regulated in order to maximize respect for autonomy. They can be justified for the protection of public health or for the protection of the rights and freedoms of others in accordance with Article 27 of the Declaration on "Limitations on the application of the principles" (see section III.1.4 of this Report). However, there are other external circumstances that may affect the capacity to make autonomous choices.

99. While, in theory, the principle of the systematic seeking of informed consent is universally acknowledged, its effective execution may face operational limits that cannot be ignored. Its effective implementation may be threatened by circumstances, for example in emergency treatment or certain pathologies such as oncology. Furthermore, there may be additional constraints due to different social, economic or cultural contexts. Developing countries for example, whilst in tune with the universally accepted principle of consent, are behind in the measures - particularly legal measures - meant to accompany compliance with the principle. While certain sorts of constraints are obvious and can be guarded against, for others, which are just as real, it may be difficult to devise preventive measures.

III.3.1. Economic context

100. In disadvantaged economic contexts where the demand for treatment is particularly great and where health systems have difficulty in responding adequately, there may be difficulties in adhering to or applying the principle of informed consent in the framework of medical practice. Different reasons can lie at the heart of these difficulties.

Level of training of medical professionals

101. The health-care system of many developing countries is based on a health-care pyramid with the basic level that can range from the infirmary with community health officials, to the health centre with a nurse and, at the top, the element of reference formed by the hospital complex with the different categories of health-care personnel including doctors. Nevertheless as each health professional treats within the limits of their competence it is necessary for them to provide the requisite information to patients in order to give an informed consent.

The lack of time for the number of patients

102. In such health structures, facilities are generally understaffed in relation to the demand for care. Whereas in certain European countries there is an average of 300 doctors for 100,000 inhabitants, there are 100 times less in certain African countries (1 to 5 doctors for 100,000 inhabitants). Adequate information can be difficult to carry out in the context of a constant work overload. Nevertheless, no practitioner should be relieved of the responsibility to make the best possible efforts to inform the patients they treat.

The lack of means of health-care professionals

103. In a socio-economical context where there is no social coverage for an illness, where means are limited and access to certain therapies problematic, there can be an issue of conscience for a doctor to inform, without this information being able to lead to any action of adequate treatment. This may be the case in certain pathologies, for example cancer, where the practitioner, in the absence of offering the possibility of appropriate interventions, may have only palliative care to propose. The relevance of dispensing complete information under these conditions may therefore be disputable, added to the fact there exists even in countries that have adequate means, the notion of to what extent a patient can bear information (tolerable truth).

The lack of means of populations for covering their health care

104. In many developing countries, the lack of social provision for health-care coverage and the lack of sufficient revenue lead to pressure to consent where consent is seen as a means to accessing care. Under these conditions, it can be feared that giving consent is just a means to health care. Furthermore, in certain cases, the lack of confidence in the equity of access to means available can put in doubt the information given and encourage corrupt practices.

105. In light of the reflections above it would appear that the systematic application of the principles of information and obtaining consent is linked to the appropriate qualification of health-care professionals as well as to the presence of material and human resources virtually non-existent in such contexts (insufficient number of qualified personnel, mediation personnel, sufficient time, etc.).

III.3.2. The context of populations with a low level of education

Difficult access to information

106. In the context of a low level of education, or illiteracy, it is more difficult to give adequate information to the patient; simplification of information might result in part of the information being omitted. Sound comprehension of information can moreover become complex when those who intervene do not use the same references in approaching health problems (scientific versus mystic, supernatural).

107. A way of mitigating these difficulties is to encourage information / educational / communication systems through a multisectoral approach in communities, the development of suitable tools to vehicle information, the training of health-care professionals to deliver simple, accessible and reliable information.

108. The use of national and local languages is often recommended to facilitate better understanding and can indeed allow populations to have access to at least simplified information. But this recommendation meets operational limits insofar as certain countries are multi-ethnic and consequently there are numerous languages within a country that are not necessarily shared by the health-care professional and the patient. As a result, this language barrier calls for a third party to dispense information, which is not always possible or reliable.

109. This problem of comprehension of information given by practitioners is sometimes raised in developed countries where illiteracy is a lesser problem, but where inability to understand is due to the complexity and length of documents submitted to patients. Certain authors have in fact underlined the perverse effect of certain jurisprudences resulting in the elaboration of information and consent documents that are very difficult to understand, more destined to protecting the practitioner from being accused of delivering insufficient information rather than to clearly informing the patient. Whilst providing too much information might protect practitioners it can disempower patients.

110. It is therefore necessary to underline the importance of the clarity of the text submitted and its content that should include necessary and sufficient information for the decision to consent or refuse to consent and this in a language that is accessible to the person concerned wherever consent to treatment is sought. Even more special attention should be given in developing countries.

Difficulties in documenting consent

111. In some cases, particularly in situations concerning scientific research, it may be necessary to document that consent has been obtained. Here again, the implementation of this demand can encounter difficulties, for example:

- in societies with an oral tradition, where the value of oral consent cannot be put into question, the demand for documentation of the consent in written form can be considered as a lack of trust or even as an insult;
- in illiterate populations, where a sign at the bottom of a page may not reflect a real agreement with the content of the document.

112. Because of this, even if in principle it is necessary to strive towards the possibility of obtaining written consent, depending on the context, it would be appropriate to explore other ways of demonstrating that consent has been obtained.

III.3.3. Social and cultural context

Communal and individual consent

113. In many societies, the community is the entity in terms of which the individual is identified. The leaders of the community make decisions on behalf of its members and of the community and these are not questioned or discussed out of respect due to them because of their age, the wisdom they are supposed to have, and because they are supposed to be the guarantors of knowing what is best for the community.

114. There is a difficulty in aligning the autonomy of individuals that is embodied in Article 5 of the Declaration with certain cultural settings where communal autonomy might be thought to prevail. The expression of an individual wish that goes against these decisions can be difficult or impossible either out of fear of negative consequences for the individual (social disapproval, exclusion...) or out of respect for the leader.

115. Of course, seeking consent from an individual is indispensable even if his/her community is consulted, but the actual value of the consent of an individual, once the community has given its approval, may sometimes provoke questioning.

116. But is it clear that either individual or communal autonomy should be preferred one to another? It depends on the kind of decision which is at stake. For example, as a member of a particular cultural group a person might be approached to engage in a research project or a commercial enterprise which would provide access by the researchers or the business in question to materials or matters which might be seen as belonging to the group rather than to any individual in that group. Sometimes matters of this kind are referred to as traditional knowledge and cultural treasures. It follows that it is not the prerogative of an individual member of that group to profit individually from communal treasures or to betray such privileged knowledge to strangers without the consent of the group. In such cases, such as the exploitation of indigenous flora or fauna, communal autonomy would impose proper limits on individual autonomy.

117. However, such cases should not be used as a basis for concluding that cultural considerations can dictate that for members of some groups communal autonomy must always override individual autonomy. For example, if a group is prepared to allow outsiders to carry out research on the community as such, individuals in that community should not be obliged to offer themselves as participants in that research. They might voluntarily devolve the authority to decide for them to the community but this would not undermine respect for their autonomy. This is the import of Article 12 in the Declaration, which asserts that respect for cultural diversity and pluralism should not be used to infringe fundamental freedoms nor any of the principles set out in the Declaration, including Article 5.

Decision-making process in the family unit

118. As stated in paragraph 33, obtaining consent depends on the possible impact for third parties, in particular family members. This will get great significance in predictive medicine involving genetic testing and producing genetic data in increasing numbers of clinical settings. Human genetic data have a special status mainly, in this respect, because they may have a significant impact on the family (International Declaration on Human Genetic Data, Article 4). When genetic test is initiated in an individual, this impact on family members should be included in consent discussion. However, consent of his/her family members is not necessary.

119. In certain cases, in the social structure of many societies in particular in developing countries, especially in rural areas, the distribution of responsibilities and the decisional hierarchy in the family unit are such that the choice to be treated or not is not necessarily made by the person concerned. Health professionals must ensure that individuals should not be subjected to coercive treatment, involuntary exclusion from available treatment or unwilling participation in research as a result of these social patterns.

120. It is necessary that the issue of consent be envisaged in a more global context of education and making persons autonomous whilst keeping in mind the primacy of the interests of the person concerned in their social setting. It is necessary to ensure the respect for the will of the person concerned, and to promote education towards autonomy and individual responsibility.

The integration of information in social perceptions and religious beliefs

121. Information on the possible risks linked to a clinical practice, in particular if there is a life-threatening risk, is not necessarily perceived as a choice given to the patient to consent or not to an act insofar as life and death are dictated by a superior power and do not therefore depend on this choice. This fatalism can lead to a mechanical acceptance of what is proposed, especially if the trust in the capability and knowledge of the person proposing is total and to the extent that the consequence(s) of these acts that aim to be therapeutic are not assumed to be contingent on this person.

The authority of knowledge

122. Another aspect that exists in most societies (in both the North and the South) is the absolute trust given to 'those who know' and in particular who distribute health care often present in these societies, to the extent that consent to what is proposed is not a matter for discussion, the argument being: "Leave it to those who know, they know better than I or my child, my parent etc.". This aspect is even more acute when it concerns a poor population with a low level of education.

Constrained individuals

123 The context of constrained individuals should be taken into particular consideration as this category of people could undergo serious restriction to give actually "free" consent particularly in research. The first ethical text (the Nuremberg Code) was indeed established to ban what Nazi doctors did to constrained individuals in concentration camps.

124. Since the Nuremberg Code, unethical research on inmates has been extensively reported by different groups of protection of human subjects and remain a current issue that should draw attention.

125. So the rights of the vulnerable population represented by inmates should be safeguarded and research in this category of people should have strict limitations. If it is obvious when speaking about "constrained individuals" to consider people who are deprived of their freedom, one should not forget that other categories of people can be considered as constrained individuals. It is the case of people whose freedom to consent can be compromised by their status, which submits them to a power/authority of someone else (hierarchical position in militaries, students in respect to their teachers, young researchers in respect to their supervisors).

126. The protection of all these categories of constrained individuals should include not only research that could induce physical risks but also, what is not always taken into account those whose could lead to psychological or sociological harms.

IV. APPLICATION AND PROMOTION

127. Since consent is closely related to autonomy and responsibility, it is the decision of the person who has given his consent to accept medical intervention or to participate in a scientific research. Although consent is obtained prior to intervention and research, it is assumed that the person involved at least implicitly continues to consent as long as the intervention or research continues. However, consent may be withdrawn at any time (see 30). The person should therefore be given the opportunity to review his consent. It is also recommendable to regularly reiterate the information upon which the consent was initially based in order to make sure that the patient understands in which intervention or research he is involved.

128. In the case of scientific research, the application and implementation of the principle of consent is usually reviewed by ethics committees. To safeguard that the consent of the person involved is prior, free, express and informed, ethical review of the research requires the assessment of the information provided to all research subjects as well as the procedures to obtain consent. Ethics committees also require in many cases documentation of the consent obtained.

129. Ethics committees should play an active role in developing and promoting models and procedures for the practice and implementation of informed consent, not only in research but also in medical interventions. Ethics committees should ensure that all practices comply with the fundamental principles of the Universal Declaration on Bioethics and Human Rights. They should also ensure that the principles applied take into account the various social, cultural and economic contexts. An active role of ethics committees is particularly important to protect the rights and interests of persons without the capacity to consent.

IV.1. Teaching of information providers

130. In obtaining informed consent, the person carrying out the medical intervention or the scientific research should take into account the various categories of practices, subjects requiring special protection, and contexts. Obtaining consent also requires confidence, confidentiality and collaborative relationships. The information provided needs to be adapted to the patient and not merely delivered in a procedural manner. Obtaining consent therefore demonstrates the need for special skills and sensitivities.

131. Medical education in general and bioethics education in particular should pay particular attention to the principle of consent and to its applications. The crucial importance of informed consent in present-day healthcare and research should be underlined. Obtaining consent should be trained and practised. Sensitive issues relating to various categories of practices, subjects requiring special protection, and contexts should be discussed and analysed.

IV.2. Communication: process and materials

132. Applying the principle of consent is a process of communication, aimed at enabling research subjects, patients and, if necessary, their surrogate representatives, to make decisions and to take responsibility for those decisions. Rather than being an isolated moment in time, a sustained effort is required to make sure that the information continues to be understood.

133. In order to facilitate the process of obtaining consent, researchers and healthcare professionals should develop information materials that are comprehensible from the perspective of research subjects and patients.

134. For the application of the principle of consent in various circumstances it will be useful if experiences are exchanged and made publicly available. UNESCO's Global Ethics Observatory can be a helpful means to collect and provide experiences from many Member States, for example through setting up a database of cases, models and experiences in many practices and regions and through publishing manuals of cases from various cultures and traditions.

IV.3. Public involvement

135. Informed consent is a fundamental principle. Anyone involved in research and medical interventions should first provide consent based on adequate information. This implies that all persons should know that this principle is to be respected. Individuals, groups, communities, institutions and corporations, public and private, should therefore be made aware of the importance and relevance of this principle for research and healthcare.

136. Ethics committees at appropriate levels have a special role to play fostering debate and public awareness of the principle of consent (see Article 19 of the Declaration).

IV.4. Role of States

137. The interpretation and implementation of the principle of consent as stated in Articles 6 and 7 of the Declaration definitely require the active participation of States. These articles should serve as a framework for legislation, regulations and policy decisions within the Member States. Moreover, since experience in many domains has shown that laws or regulations are only effectively enforced if they are backed by action in education, training and information, States should also have a specific responsibility in promoting education, training and information in the fields relevant to bioethics.

V. EXECUTIVE SUMMARY AND CONCLUSIONS

138. Adopted by acclamation on 19 October 2005 by the 33rd General Conference of UNESCO, the Universal Declaration on Bioethics and Human Rights (hereafter “the Declaration”) devotes two articles to the issue of consent: Article 6 addresses the principle of consent and Article 7 covers the case of persons without the capacity to consent.

139. Aware of the difficulties that the practical application of the principle of consent - as stated in Articles 6 and 7 of the Universal Declaration on Bioethics and Human Rights (2005) - may be faced with, IBC decided to further examine this principle in order to enlighten States, organizations and citizens and support the actions they have undertaken or intend to undertake, so that the consent of a person “for any medical intervention (...) or scientific research” be the expression of his/her freedom.

140. This report should not be considered as neither exhaustive nor prescriptive. It lies within a context where the principle of consent has been, and continues to be, the subject of intense debate at both international and local levels. It should also be recalled that the principle of consent has already been dealt with in existing international standard-setting instruments within and outside the framework of the United Nations system. (More information is provided in Appendix 1 of this report). Whilst this report focuses on Articles 6 and 7 of the Declaration which address the issue of consent, these articles shall not be considered and interpreted separately from the other articles of the Declaration. As stated in Article 26, all principles “are to be understood as complementary and interrelated” and “considered in the context of the other principles, as appropriate and relevant in the circumstances”. Moreover, although this report addresses the difficulties that the application of Articles 6 and 7 of the Declaration may be faced with, it should be recalled that any limitation to their application should be by law, consistent with international human rights law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others (as stated in Article 27 of the Declaration).

Why is consent a fundamental principle in bioethics?

141. Consent is one of the basic principles of bioethics because it is closely linked to the principle of autonomy and because it reflects affirmation of human rights and human dignity which are the core values of democratic societies.

When and how should we seek consent?

142. Consent should be obtained prior to medical or scientific intervention. Even if there is a certain asymmetry in the health-care professional - patient relationship, consent should proceed as a dialogue between two partners emphasizing the importance of personal autonomy and self-determination.

What are the main elements of consent?

143. Consent is based on:

- adequate information provided by health-care professionals to patients and research participants;
- adequate understanding of the information provided; and
- freedom to consent to or to refuse an intervention proposed.

What are the most important aspects of information provided?

144. An individual has to receive comprehensible, relevant, structured and individually tailored information that makes it possible for that individual to make a decision on whether or not to accept medical intervention or to participate in scientific research.

145. Information about possible risks and benefits related to a proposed medical or scientific intervention is a key component in obtaining consent. Medical or scientific interventions may involve a complex ratio of benefits and risks and it is a duty of health-care professionals to convey to a patient or research subject this information in a comprehensible language.

146. In situations where alternative medical interventions are available, it is of paramount importance to present these alternatives to the patient in a comprehensive way and give him or her an opportunity to choose.

147. It should also be stressed that consent to a particular medical or scientific intervention implies the right to freely withdraw the consent at any time. In the case of medical interventions, the possible consequences of such a decision should be conveyed to the patient, making sure that they are understood by the patient.

What are the different forms of expressing consent?

148. Consent should be 'express', i.e. leaving no doubt as to the will of the person concerned. It may be expressed in writing, orally or even by gesture according to circumstances and cultures. Whether consent is verbal or written may depend on the type of the intervention provided (e.g., consent to scientific research should usually be written) as well as on cultural circumstances (e.g., in some societies, because of illiteracy, oral consent may be preferable).

149. Advance directives have been more and more often considered as a means to express the autonomy of the person with regard to decisions on his/her health if he/she becomes unable to give valid consent (e.g., clinically confused or unconscious patients).

150. In some cases consent procedures are supervised by special bodies. In the case of biomedical research, for example, the information sheet and consent form together with other relevant documents should be reviewed by ethics committees.

Are consent procedures different in various circumstances of application?

151. While the principle of the systematic seeking of consent is universally acknowledged, its effective implementation may be threatened by different circumstances depending on different types of practice, subjects and contexts. With regard to practices, Article 6 of the Declaration makes a distinction between preventive, diagnostic and therapeutic medical interventions and scientific research. A distinction can also be made between persons able to consent and those not able to consent requiring special protection. Finally, additional constraints may be due to different social, economic or cultural contexts.

What are the most important features of consent in clinical practice?

152. Obtaining consent should be a requisite sine qua non. However, consent procedures may take the greatest variety of forms, particularly in clinical practice and will depend on:

- the duration and the quality of the relationship between the provider and the recipient of health care,
- the invasive character of the procedure,
- the potential benefits and possible side-effects,
- the possible impact for third parties, in particular family members,
- the economic consequences, especially when the related cost is not or not entirely covered by a health insurance mechanism.

153. On the one hand, there are a number of routine, simple non-invasive interventions in daily medical practice the nature of which can be assumed to be known by the ordinary patient and that can be undertaken without requiring an express consent, on the understanding that the fact that the patient shows no opposition can be considered a tacit

agreement (e.g. communication between a patient and a doctor while measuring blood pressure as a part of clinical examination). On the other hand, the more invasive the intervention is and the more severe physical, psychological and/or socio-economic its consequences are, the more express and formalized the consent will need to be.

What are the most important features of consent in biomedical/clinical research?

154. In biomedical/clinical research, the issue of consent and the practical circumstances of obtaining it vary according to additional criteria, in particular:

- whether the research is on healthy volunteers,
- whether or not patients taking part in a research are likely to benefit from it directly or indirectly.

155. Participation in biomedical/clinical research should be described in precise terms in writing and requires express, formal and preferably written consent. In addition, consent forms and information sheets provided to research participants should be approved by ethics committees prior to the commencement of a research.

156. Generally, care should be taken to ensure that research participants are not under pressure to participate. In addition, there are several other aspects to be considered, in relation to the civil status and capacity to consent of the participants in research (minors, unconscious patients, etc).

Are there exceptions to consent procedures in epidemiological research?

157. In situations where opportunities to use already collected data/material for another research only appear later on, the issue of consent becomes a delicate one. For such situations countries, ethical review boards or professional societies should establish specific regulations, including examination by expert bodies, to eventually waive the individual consent requirement. In addition, individuals should have a right to withdraw from the research project or be entitled in some way to protect their rights. It is not acceptable to ask participants in a research project to give an *overall prior consent* (so-called "blanc consent") to the effect that they would agree to any study that can be carried out with the data/material they provided, unless the data/material be irretrievably unlinked to the participants.

What are examples of public health interventions that are carried on without consent of individuals?

158. Public health interventions aim at preventing, eradicating or alleviating a problem of importance for the whole population – or groups within it. In situations where the disease or behaviour of an individual may have serious public health consequences, it may be justified, for the protection of public health or for the protection of the rights and freedoms of others, to interfere with the self-determination of individuals. Examples of such situations are enforced quarantine to limit the spread of a detrimental epidemic (e.g. plague), compulsory immunization of an entire population or categories within it (e.g. health-care professionals) to reduce the spread of communicable diseases, periodic health controls of professionals in jobs involving serious risks, hospitalization and treatment of certain forms of communicable diseases or mental illnesses.

What are the most important features of consent in emergency situations?

159. Emergency situations pose specific questions because of the need to act rapidly to save the patient's life and/or limit consequences to the maximum possible extent. In addition, the patient might be confused or, worse, in an unconscious condition and thus cannot give a valid determination. In such situations, where there is no known or likely preference of the patient, the health-care professionals have a duty to consult an appropriate representative, if available. As soon as the person concerned is once again in a position to decide, he/she should be fully informed of the situation and of the medical measures undertaken while

he/she could not be aware of them, and his/her consent should be obtained before going further with the treatment. Research projects in emergency situations pose similar, but to some extent more demanding challenges which are dealt with differently in different countries.

What are the most important features of consent in organ, tissue and cell donation?

160. In situations of post-mortem donation some countries have adopted the practice of presumed consent, based on the view that every deceased person is a potential donor, except when in life the subject had expressly stated the opposite. In other countries express consent is required, i.e. the explicit authorization by the subject or, after his death, by the relatives.

161. In situations of living donation the conditions for obtaining consent can be more adequately fulfilled, because of the possibility of interaction with the donor. In practice, however, the autonomy of the living donor can be compromised. Special care should therefore be taken to guarantee that: (a) the donor is fully informed of the possible adverse effects and long-term consequences of the donation; (b) emotional pressures have not compromised the free consent of the donor; and (c) consent is given without inducement by financial or other personal gain.

What procedures should be followed when dealing with persons unable to consent?

162. Article 7 of the Declaration stipulates that special protection is to be given to persons who do not have the capacity to consent to research or medical practice. Persons without the capacity to consent can be identified as those who, for reasons internal to themselves, do not have the capacity to make autonomous choices irrespective of their external circumstances. Various groups of people have been traditionally labelled in this way. They include people with learning difficulties, the mentally ill, children, confused elderly and unconscious people.

163. The general safeguard of the freedom of patients in these situations is that no judgment of capacity to consent should be called for unless there is evidence to undermine the normal assumption that people are able to decide for themselves.

164. They should be involved in the decision-making process according to their age, maturity and/or degree of capacity to consent. In some cases, however, a representative in charge of defining the best interest of the person is needed. The question of who can be a legitimate representative has to be addressed and depends significantly on legal, social and cultural features.

Is scientific research on persons unable to consent justifiable?

165. If studies can be undertaken with scientific validity on persons who can provide their own informed and free consent, they should not be carried out on persons unable to consent, except when there is a likelihood that the project will bring them direct benefit or when no comparable study can be undertaken – and relevant results obtained – with other patients. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category.

How does the practice of consent depend on the economic context?

166. In disadvantaged economic contexts where the demand for treatment is particularly great and where health systems have difficulty in responding adequately (because of lack of health-care professionals, lack of infrastructure, lack of drugs, lack of training, etc.), there may be difficulties in adhering to or applying the principle of informed consent in the framework of medical practice.

167. Such difficulties should not be used as an argument to diminish the role of consent. On the contrary, attempts should be made to find ways to implement this principle even in such circumstances.

How do social and cultural contexts influence consent?

168. It is necessary that the issue of consent be envisaged in a more global context of education and making persons autonomous whilst keeping in mind the primacy of the interests of the person concerned in their social setting. It is necessary to ensure the respect for the will of the person concerned, and to promote education towards autonomy and individual responsibility.

169. One of the most complex situations arises in societies where communal forms of decision making prevail. In such circumstances the exercise of individual consent procedures becomes very problematic. Seeking consent from an individual is indispensable even if his/her community is consulted, but the actual value of the consent of an individual, once the community has given its approval, may sometimes provoke questioning. Decision-making in the family unit might pose similar problems as well. However, it should be noted that although it is important to observe and respect values of different cultures, these values should not infringe upon fundamental freedoms.

170. The context of constrained individuals should be taken into particular consideration as this category of people could undergo serious restriction to give actually 'free' consent particularly in research.

International Legal Context

As a consequence of the medical abuses carried out during the Second World War, the principle of consent was stated in the Nuremberg Code (1947) – the first international basic ethical text – as the first of the ten rules to be respected in conducting research involving the human subject: *“The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision”*.

Within the UN system, the principle of the free consent of a person undergoing scientific or medical experimentation was then stated explicitly in article 7 of the International Covenant on Civil and Political Rights (1966). Where the person concerned is not in a position to consent, this article states that a double condition must be met, namely that consent must be given in the manner prescribed by law, and furthermore that the competent individual or authority must be guided by the best interest of the person concerned.

Other UN instruments stipulate provisions on consent in specific cases, for example the United Nations Convention on the Rights of the Child of 20 November 1989 guarantees *“the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child”* (Art. 12).

At a more general international level, the Declaration of Helsinki of the World Medical Association (WMA) on Ethical Principles for Medical Research Involving Human Subjects (adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000) as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) (adopted in 1982 and amended in 1993 and 2002) provide detailed provisions on consent required in the field research.

At regional level, It should also be recalled that the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe (1997) and its Protocols devote several articles to the issue of consent.

Finally, before the Universal Declaration on Bioethics and Human Rights was adopted in 2005, UNESCO already contributed to the existing international legal framework on this issue.

The **Universal Declaration on the Human Genome and Human Rights** – adopted by the General Conference of UNESCO in 1997 and endorsed by the United Nations General Assembly in 1998 – deals with the issue of consent in Article 5⁽¹⁾ within the specific

1. *“(a) Research, treatment or diagnosis affecting an individual’s genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.*

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person’s best interest.

(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.

(d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

(e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the

framework of research, treatment or diagnosis affecting an individual's genome. The various paragraphs of article 5 are aimed at protecting the rights of the persons concerned, stressing the need to prevent any practices which might be contrary to human dignity, freedom and human rights. The article as a whole sets forth the basic principles that should govern any intervention on the human genome: the principle of prior, free and informed consent, which has as a corollary the right of an individual to refuse to be informed about his or her own genetic data; and all other principles founded on the autonomy of the individual, which follows from the individual's right to privacy.

In the **International Declaration on Human Genetic Data** (2003), a number of provisions deal with the issue of consent related to the specific subject of human genetic data and further develop the provisions of the Universal Declaration on the Human Genome and Human Rights on this issue. Article 8⁽²⁾ deals with consent to the collection of biological samples and human genetic data, Article 9⁽³⁾ is devoted to the withdrawal of consent and Article 10⁽⁴⁾ addresses the issue of the right to decide whether or not to be informed about research results.

health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights."

2. *"a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.*

(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.

(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

(d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when they have important implications for the health of the person and have regard to his or her best interest."

3. *"(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.*

(b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed."

4. *"When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results."*

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