



## **Explanatory Report to 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 \***

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I. This Explanatory Report to the Convention on human rights and biomedicine was drawn up under the responsibility of the Secretary General of the Council of Europe, on the basis of a draft prepared, at the request of the Steering Committee on Bioethics (CDBI), by Mr Jean MICHAUD (France), Chairman of the CDBI. It takes into account the discussions held in the CDBI and its Working Group entrusted with the drafting of the Convention; it also takes into account the remarks and proposals made by Delegations.

II. The Committee of Ministers has authorised the publication of this Explanatory Report on 17 December 1996.

III. The Explanatory Report is not an authoritative interpretation of the Convention. Nevertheless it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the Convention and to better understand the scope of its provisions.

### **Introduction**

1. For several years now, the Council of Europe, through the work of the Parliamentary Assembly and of the *ad hoc* Committee of Experts on Bioethics (CAHBI), later renamed the Steering Committee on Bioethics (CDBI), has concerned itself with the problems confronting mankind as a result of advances in medicine and biology. At the same time, a number of countries have done their own internal work on these topics, and this work is proceeding. So far, therefore, two types of endeavour have been undertaken, one at a national and the other at international level.

2. Basically, these studies are the fruit of observation and concern: observation of the radical developments in science and their applications to medicine and biology, that is fields in which people are directly involved and concern about the ambivalent nature of many of these advances. The scientists and practitioners behind them have worthy aims and often attain them. But some of the known or alleged developments of their work are taking or could potentially take a dangerous turn, as a result of a distortion of the original objectives. Science, with its new complexity and extensive ramifications, thus presents a dark side or a bright side according to how it is used.

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(\*) The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

3. It has subsequently become necessary to ensure that the beneficial side prevails by developing awareness of what is at stake and constantly reviewing all the possible consequences. No doubt the ethics committees and other national bodies and legislators, as well as the international organisations, have already applied themselves to this task, but their efforts have remained either restricted to a particular geographical area or incomplete because of their focus on a particular topic. On the other hand, common values are more often than not claimed as a basis for the various texts, opinions and recommendations. But differences may, nonetheless, become apparent in connection with certain aspects of the problems dealt with. Even simple definitions may give rise to profound differences.

### **Drafting of a Convention**

4. It has consequently become apparent that there was a need to make a greater effort to harmonise existing standards. In 1990, at their 17th Conference (Istanbul, 5-7 June 1990), the European Ministers of Justice, following the proposal of Ms Catherine Lalumière, Secretary General of the Council of Europe, adopted Resolution No. 3 on bioethics which recommended that the Committee of Ministers instruct the CAHBI to examine the possibility of preparing a framework convention "setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences". In June 1991, taking up the contents of a report submitted on behalf of the Committee of science and technology by Dr Marcelo Palacios (see Document 6449), the Parliamentary Assembly recommended, in its Recommendation 1160, that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects". In September of the same year the Committee of Ministers, chaired by Mr Vincent Tabone, instructed the CAHBI "to prepare, in close co-operation with the Steering Committee for Human Rights (CDDH) and the European Health Committee (CDSP) ... a framework Convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the biomedical sciences and Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings".

5. In March 1992 the CAHBI, then the CDBI, which has been chaired in turn by Mrs Paula KOKKONEN (Finland), Dr Octavi QUINTANA (Spain) and Mrs Johanna KITS NIEUWENKAMP née Storm van'SGravesande (The Netherlands), set up a Working Party to prepare the draft Convention, which was chaired by Dr Michael ABRAMS (United Kingdom). Until his untimely death, Mr Salvatore PUGLISI (Italy) was a member of this Group, after having been Chair of the Study Group set up to examine the feasibility of the draft Convention.

6. In July 1994, a first version of the draft Convention was subjected to public consultation and was submitted for an opinion to the Parliamentary Assembly. Taking account of this opinion and of several other positions taken, a final draft was established by the CDBI on 7 June 1996 and was submitted to the Parliamentary Assembly for an opinion. The latter put forward Opinion No. 198 on the basis of a report submitted on behalf of the Committee on Science and Technology by Mr Gian-Reto PLATTNER and for the Committee on Legal Affairs and Human Rights and the Social, Health and Family Affairs Committee by Messrs Walter SCHWIMMER and Christian DANIEL respectively. The Convention was adopted by the Committee of Ministers on 19 November 1996. It was opened for signature on 4 April 1997.

### **Structure of the Convention**

7. The Convention sets out only the most important principles. Additional standards and more detailed questions should be dealt with in additional protocols. The Convention as a whole will thus provide a common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine.

## Comments on the provisions of the Convention

### Title

8. The title of the instrument is "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".

9. The term "Human Rights" refers to the principles laid down in the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, which guarantee protection of such rights. The two Conventions share not only the same underlying approach but also many ethical principles and legal concepts. Indeed, this Convention elaborates some of the principles enshrined in the European Convention for the Protection of Human Rights. The concept of the human being has been used because of its general character. The concept of human dignity, which is also highlighted, constitutes the essential value to be upheld. It is at the basis of most of the values emphasised in the Convention.

10. The phrase "application of biology and medicine", was preferred to "life sciences" in particular, which was considered too broad. It is used in Article 1 and restricts the scope of the Convention to human medicine and biology, thereby excluding animal and plant biology insofar as they do not concern human medicine or biology. The Convention thus covers all medical and biological applications concerning human beings, including preventive, diagnostic, therapeutic and research applications.

### Preamble

11. Various international instruments already provide protection and guarantees in the field of human rights, both individual and social: the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of the Child, the Convention for the Protection of Human Rights and Fundamental Freedoms, the European Social Charter. Several instruments of a more specific nature prepared by the Council of Europe are also relevant, such as the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.

12. They must now be supplemented by other texts so that full account is taken of the potential implications of scientific actions.

13. The principles enshrined in these instruments remain the basis of our conception of human rights; hence they are set out at the beginning of the preamble to the Convention, of which they are the cornerstone.

14. Starting with the preamble, however, it was necessary to take account of the actual developments in medicine and biology, while indicating the need for them to be used solely for the benefit of present and future generations. This concern has been affirmed at three levels:

– The first is that of the individual, who had to be shielded from any threat resulting from the improper use of scientific developments. Several articles of the Convention illustrate the wish to make it clear that pride of place ought to be given to the individual: protection against unlawful interference with the human body, prohibition of the use of all or part of the body for financial gain, restriction of the use of genetic testing, etc.

– The second level relates to society. Indeed, in this particular field, to a greater extent than in many others, the individual must also be considered to constitute part of a social corpus sharing a number of ethical principles and governed by legal standards. Whenever choices are involved in regard to the application of certain developments, the latter must be recognised and endorsed by the community. This is why public debate is so important and is given a place in the Convention. Nevertheless, the

interests at stake are not equal; as indicated in Article 2, they are graded to reflect the priority in principle attached to the interests of the individual as opposed to those of science or society solely. The adjective "alone" makes it clear that care must be taken not to neglect the latter; they must come immediately after the interests of the individual. It is only in very precise situations, and subject to the respect of strict conditions that the general interest, as it is defined in Article 26, would take priority.

– The third and final concern relates to the human species. Many of the current achievements and forthcoming advances are based on genetics. Progress in knowledge of the genome is producing more ways of influencing and acting on it. This knowledge already enables considerable progress to take place in the diagnosis and, sometimes, in the prevention of an increasing number of diseases. There are reasons to hope that it could also enable therapeutic progress to take place. However, the risks associated with this growing area of expertise should not be ignored. It is no longer the individual or society that may be at risk but the human species itself. The Convention sets up safeguards, starting with the preamble where reference is made to the benefits to future generations and to all humanity, while provision is made throughout the text for the necessary legal guarantees to protect the identity of the human being.

15. The preamble refers to the developments in medicine and biology which should be used only for the benefit of present and future generations and not be diverted in ways that run counter to their proper objective. It proclaims the respect due to man as an individual and as a member of the human species. It concludes that progress, human benefit and protection can be reconciled if public awareness is aroused as a result of an international instrument devised by the Council of Europe in line with its vocation. Stress is laid on the need for international co-operation to extend the benefits of progress to the whole of mankind.

## **Chapter I – General provisions**

### **Article 1 – Purpose and object**

16. This article defines the Convention's scope and purpose.

17. The aim of the Convention is to guarantee everyone's rights and fundamental freedoms and, in particular, their integrity and to secure the dignity and identity of human beings in this sphere.

18. The Convention does not define the term "everyone" (in French "toute personne"). These two terms are equivalent and found in the English and French versions of the European Convention on Human Rights, which however does not define them. In the absence of a unanimous agreement on the definition of these terms among member States of the Council of Europe, it was decided to allow domestic law to define them for the purposes of the application of the present Convention.

19. The Convention also uses the expression "human being" to state the necessity to protect the dignity and identity of all human beings. It was acknowledged that it was a generally accepted principle that human dignity and the identity of the human being had to be respected as soon as life began.

20. The second paragraph of the Article specifies that each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention. This paragraph indicates that the internal law of the Parties shall conform to the Convention. Conformity between the Convention and domestic law may be achieved either by applying directly the Convention's provisions in domestic law or by enacting the necessary legislation to give effect to them. With regard to each provision, the means will have to be determined by each Party in accordance with its constitutional law and taking into account the nature of the provision in question. In this respect, it should be noted that the Convention contains a number of provisions which may, under the domestic law of many States, qualify as directly applicable ("self-executing provisions"). This is the case, particularly, of the provisions formulating individual

rights. Other provisions contain more general principles which may require the enactment of legislation in order that effect be given to them in domestic law.

### **Article 2 – Primacy of the human being**

21. This article affirms the primacy of the human being over the sole interest of science or society. Priority is given to the former, which must in principle take precedence over the latter in the event of a conflict between them. One of the important fields of application of this principle concerns research, as covered by the provisions of Chapter V of this Convention.

22. The whole Convention, the aim of which is to protect human rights and dignity, is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light.

### **Article 3 – Equitable access to health care**

23. This article defines an aim and imposes an obligation on States to use their best endeavours to reach it.

24. The aim is to ensure equitable access to health care in accordance with the person's medical needs. "Health care" means the services offering diagnostic, preventive, therapeutic and rehabilitative interventions, designed to maintain or improve a person's state of health or alleviate a person's suffering. This care must be of a fitting standard in the light of scientific progress and be subject to a continuous quality assessment.

25. Access to health care must be equitable. In this context, "equitable" means first and foremost the absence of unjustified discrimination. Although not synonymous with absolute equality, equitable access implies effectively obtaining a satisfactory degree of care.

26. The Parties to the Convention are required to take appropriate steps to achieve this aim as far as the available resources permit. The purpose of this provision is not to create an individual right on which each person may rely in legal proceedings against the State, but rather to prompt the latter to adopt the requisite measures as part of its social policy in order to ensure equitable access to health care.

27. Although States are now making substantial efforts to ensure a satisfactory level of health care, the scale of this effort largely depends on the volume of available resources. Moreover, State measures to ensure equitable access may take many different forms and a wide variety of methods may be employed to this end.

### **Article 4 – Professional standards**

28. This article applies to doctors and health care professionals generally, including psychologists whose interactions with patients in clinical and research settings can have profound effects and social workers who are members of teams involved in the decision making process or in the carrying out of interventions. From the term "professional standards" it follows that it does not concern persons other than health care professionals called upon to perform medical acts, for example in an emergency.

29. The term "intervention" must be understood here in a broad sense; it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment or rehabilitation or in a research context.

30. All interventions must be performed in accordance with the law in general, as supplemented and developed by professional rules. In some countries these rules take the form of professional codes of ethics (drawn up by the State or by the profession), in others codes of medical conduct, health legislation, medical ethics or any other means of guaranteeing the rights and interests of the patient, and which may take account of any right of conscientious

objection by health care professionals. The Article covers both written and unwritten rules. When there is a contradiction between different rules, the law provides the means of resolving the conflict.

31. The content of professional standards, obligations and rules of conduct is not identical in all countries. The same medical duties may vary slightly from one society to another. However, the fundamental principles of the practice of medicine apply in all countries. Doctors and, in general, all professionals who participate in a medical act are subject to legal and ethical imperatives. They must act with care and competence, and pay careful attention to the needs of each patient.

32. It is the essential task of the doctor not only to heal patients but also to take the proper steps to promote health and relieve pain, taking into account the psychological well-being of the patient. Competence must be determined primarily in relation to the scientific knowledge and clinical experience appropriate to a profession or speciality at a given time. The current state of the art determines the professional standard and skill to be expected of health care professionals in the performance of their work. In following the progress of medicine, it changes with new developments and eliminates methods which do not reflect the state of the art. Nevertheless, it is accepted that professional standards do not necessarily prescribe one line of action as being the only one possible: recognised medical practice may, indeed, allow several possible forms of intervention, thus leaving some freedom of choice as to methods or techniques.

33. Further, a particular course of action must be judged in the light of the specific health problem raised by a given patient. In particular, an intervention must meet criteria of relevance and proportionality between the aim pursued and the means employed. Another important factor in the success of medical treatment is the patient's confidence in his or her doctor. This confidence also determines the duties of the doctor towards the patient. An important element of these duties is the respect of the rights of the patient. The latter creates and increases mutual trust. The therapeutic alliance will be strengthened if the rights of the patient are fully respected.

## **Chapter II – Consent**

### **Article 5 – General rule**

34. This article deals with consent and affirms at the international level an already well-established rule, that is that no one may in principle be forced to undergo an intervention without his or her consent. Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person. This rule makes clear patients' autonomy in their relationship with health care professionals and restrains the paternalist approaches which might ignore the wish of the patient. The word "intervention" is understood in its widest sense, as in Article 4 – that is to say, it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research.

35. The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone. Article 5, paragraph 2, mentions the most important aspects of the information which should precede the intervention but it is not an exhaustive list: informed consent may imply, according to the circumstances, additional elements. In order for their consent to be valid the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. This information must include the purpose, nature and consequences of the intervention and the risks involved. Information on the risks involved in the intervention or in alternative courses of action must cover not only the risks inherent in the type of intervention contemplated, but also any risks related to the individual characteristics of each patient, such as age or the existence of other pathologies. Requests for additional information made by patients must be adequately answered.

36. Moreover, this information must be sufficiently clear and suitably worded for the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause.

37. Consent may take various forms. It may be express or implied. Express consent may be either verbal or written. Article 5, which is general and covers very different situations, does not require any particular form. The latter will largely depend on the nature of the intervention. It is agreed that express consent would be inappropriate as regards many routine medical acts. The consent is therefore often implicit, as long as the person concerned is sufficiently informed. In some cases, however, for example invasive diagnostic acts or treatments, express consent may be required. Moreover, the patient's express, specific consent must be obtained for participation in research or removal of body parts for transplantation purposes (see Articles 16 and 19).

38. Freedom of consent implies that consent may be withdrawn at any time and that the decision of the person concerned shall be respected once he or she has been fully informed of the consequences. However, this principle does not mean, for example, that the withdrawal of a patient's consent during an operation should always be followed. Professional standards and obligations as well as rules of conduct which apply in such cases under Article 4 may oblige the doctor to continue with the operation so as to avoid seriously endangering the health of the patient.

39. Furthermore, Article 26 of the Convention, as well as Article 6 concerning protection of persons not able to consent, Article 7 concerning protection of persons who have mental disorders and Article 8 concerning emergency situations, define the instances in which the exercise of the rights contained in the Convention and hence the need for consent may be limited.

40. Information is the patient's right, but as provided for in Article 10, the patient's possible wish not to be informed must be observed. This does not, however, obviate the need to seek consent to the intervention proposed to the patient.

#### **Article 6 – Protection of persons not able to consent**

41. Some individuals may not be able to give full and valid consent to an intervention due to either their age (minors) or their mental incapacity. It is therefore necessary to specify the conditions under which an intervention may be carried out on these people in order to ensure their protection.

42. The incapacity to consent referred to in this article must be understood in the context of a given intervention. However, account has been taken of the diversity of legal systems in Europe: in some countries the patient's capacity to consent must be verified for each intervention taken individually, while in others the system is based on the institution of legal incapacitation, whereby a person may be declared incapable of consenting to one or several types of act. Since the purpose of the Convention is not to introduce a single system for the whole of Europe but to protect persons who are not able to give their consent, the reference in the text to domestic law seems necessary: it is for domestic law in each country to determine, in its own way, whether or not persons are capable of consenting to an intervention and taking account of the need to deprive persons of their capacity for autonomy only where it is necessary in their best interests.

43. However, in order to protect the fundamental rights of the human being, and in particular to avoid the application of discriminatory criteria, paragraph 3 lists the reasons why an adult may be considered incapable of consenting under domestic law, namely a mental disability, a disease or similar reasons. The term "similar reasons" refers to such situations as accidents or states of coma, for example, where the patient is unable to formulate his or her wishes or to communicate them (see also paragraph 57 below on emergency situations). If adults have been declared incapable but at a certain time do not suffer from a reduced mental capacity (for

example because their illness improves favourably), they must, according to Article 5, themselves consent.

44. Whenever a person is acknowledged to be incapable of giving consent, the Convention establishes the principle of protection whereby, according to paragraph 1, the intervention must be for the direct benefit of the person. Deviation from this rule is possible in only two cases, covered by Articles 17 and 20 of the Convention, on medical research and the removal of regenerative tissue respectively.

45. As indicated before, the second and third paragraphs prescribe that when a minor (paragraph 2) or an adult (paragraph 3) is not capable of consenting to an intervention, the intervention may be carried out only with the consent of parents who have custody of the minor, his or her legal representative or any person or body provided for by law. However, as far as possible, with a view to the preservation of the autonomy of persons with regard to interventions affecting their health, the second part of paragraph 2 states that the opinion of minors should be regarded as an increasingly determining factor in proportion to their age and capacity for discernment. This means that in certain situations which take account of the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. This could even lead to the conclusion that the consent of a minor should be necessary, or at least sufficient for some interventions. Note that the provision of the second sub-paragraph of paragraph 2 is consistent with Article 12 of the United Nations Convention on the Rights of the Child, which stipulates that "States Parties shall assure 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".

46. Furthermore, the participation of adults not able to consent in decisions must not be totally ruled out. This idea is reflected in the obligation to involve the adult in the authorisation procedure whenever possible. Thus, it will be necessary to explain to them the significance and circumstances of the intervention and then obtain their opinion.

47. Paragraph 4 of this article draws a parallel with Article 5 concerning consent in general, stating that the person or body whose authorisation is required for the intervention to take place must be given adequate information about the consequences and risks involved.

48. According to paragraph 5, the person or body concerned may withdraw their authorisation at any time, provided that this is done in the interest of the person not able to consent. The first duty of doctors or other health care professionals is to their patient and it is also part of the professional standard (Article 4) to act in the interest of the patient. It is, in fact, a duty of the doctor to protect the patient against decisions taken by a person or body whose authorisation is required, which are not in the interest of the patient; in this respect, national law should provide adequate recourse procedures. The subordination of consent (or its withdrawal) to the interest of the patient is in keeping with the objective of protecting the person. While a person capable of giving consent to an intervention has the right to withdraw that consent freely, even if this appears to be contrary to the person's interest, the same right must not apply to an authorisation given for an intervention on another person, which should be retractable only if this is in the interest of that third party person.

49. It was not considered necessary to provide in this article for a right of appeal against the decision of the legal representative to authorise or refuse to authorise an intervention. In the very terms of paragraphs 2 and 3 of this article, the intervention may be carried out only "with the authorisation of his or her representative or an authority or a person or body provided for by law", which in itself implies the possibility of appealing to a body or authority in the manner provided for in domestic law.

#### **Article 7 – Protection of persons who have mental disorder**

50. This article deals with the specific question of the treatment of patients suffering from mental disorders. On the one hand it constitutes an exception to the general rule of consent for persons



able to consent (Article 5), but whose ability to decide on a proposed treatment is severely impaired by their very mental disorder. On the other hand, it guarantees the protection of these people by limiting the number of instances in which they may be subjected to treatment for their mental disorders without their consent, by subjecting such interventions to specific conditions. Moreover, this Article does not provide for the specific emergency situations mentioned in Article 8.

51. The first condition is that the person must be suffering from a mental disorder (*trouble mental* in French). In order for the article to apply, an impairment of the person's mental faculties must be observed.

52. The second condition is that the intervention is necessary to treat specifically these mental disorders. For every other type of intervention, the practitioner must therefore seek the consent of the patient, insofar as this is possible, and the assent or refusal of the patient must be followed. The refusal to consent to an intervention may only be disregarded under those circumstances prescribed by law and where a failure to intervene would result in serious harm to the health of the individual (or to the health and safety of others). In other words, if persons capable of consent refuse an intervention not aimed at treating their mental disorder, their opposition must be respected in the same way as for other patients capable of consent.

53. A number of member States have laws about the treatment of patients with mental illness of a serious nature who either are compulsorily detained or have a life-threatening medical emergency. They permit intervention for certain serious situations, such as the treatment of a serious somatic illness in a psychotic patient or also for certain serious medical emergencies (for example acute appendicitis, an overdose of medication or the case of a woman with a severe psychotic illness who has a ruptured ectopic pregnancy). In such cases the legislation permits a life-saving treatment, so long as the physician concerned believes it is proper to do so. The procedure is covered by Article 6 (Protection of persons not able to consent) or Article 8 (Emergency situations).

54. The third condition is that, without treatment of his or her mental disorder, serious harm is likely to result to the person's health. Such a risk exists, for example, when a person suffers from a suicidal tendency and is therefore a danger to himself or herself. The article is concerned only with the risk to the patient's own health, whereas Article 26 of the Convention permits patients to be treated against their will in order to protect other people's rights and freedoms (for example, in the event of violent behaviour). On the one hand, therefore, the article protects the person's health (in so far as treatment of the mental disorder without consent is allowed when failure to administer the treatment would seriously harm the person's health), and on the other hand it protects their autonomy (since treatment without consent is prohibited when failure to administer the treatment represents no serious risk to the person's health).

55. The last condition is that the protective conditions laid down in national law must be observed. The article specifies that these conditions must include appropriate supervisory, control and appeal procedures, such as mediation by a judicial authority. This requirement is understandable in view of the fact that it will be possible for an intervention to be carried out on a person who has not consented to it; it is therefore necessary to provide an arrangement for adequately protecting the rights of that person. In this connection, Recommendation No. R (83) 2 of the Committee of Ministers of the Council of Europe concerning the legal protection of persons suffering from mental disorder placed as involuntary patients establishes a number of principles which must be respected during psychiatric treatment and placement. The Hawaii Declaration of the World Psychiatric Association of 10 July 1983 and its revised versions and the Madrid Declaration of 25 August 1996, as well as Parliamentary Assembly Recommendation 1235 (1994) on psychiatry and human rights, should also be mentioned.

#### **Article 8 – Emergency situations**

56. In emergencies, doctors may be faced with a conflict of duties between their obligations to provide care and seek the patient's consent. This article allows the practitioner to act immediately in such situations without waiting until the consent of the patient or the

authorisation of the legal representative where appropriate can be given. As it departs from the general rule laid down in Articles 5 and 6, it is accompanied by conditions.

57. First, this possibility is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent. The article applies both to persons who are capable and to persons who are unable either *de jure* or *de facto* to give consent. An example that might be put forward is that of a patient in a coma who is thus unable to give his consent (see also paragraph 43 above), or that of a doctor who is unable to contact an incapacitated person's legal representative who would normally have to authorise an urgent intervention. Even in emergency situations, however, health care professionals must make every reasonable effort to determine what the patient would want.

58. Next, the possibility is limited solely to medically necessary interventions which can not be delayed. Interventions for which a delay is acceptable are excluded. However, this possibility is not reserved for life-saving interventions.

59. Lastly, the article specifies that the intervention must be carried out for the immediate benefit of the individual concerned.

#### **Article 9 – Previously expressed wishes**

60. Whereas Article 8 obviates the need for consent in emergencies, this article is designed to cover cases where persons capable of understanding have previously expressed their consent (that is either assent or refusal) with regard to foreseeable situations where they would not be in a position to express an opinion about the intervention.

61 The article therefore covers not only the emergencies referred to in Article 8 but also situations where individuals have foreseen that they might be unable to give their valid consent, for example in the event of a progressive disease such as senile dementia.

62. The article lays down that when persons have previously expressed their wishes, these shall be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progress in medicine.

### **Chapter III – Private life and right to information**

#### **Article 10 – Private life and right to information**

63. The first paragraph establishes the right to privacy of information in the health field, thereby reaffirming the principle introduced in Article 8 of the European Convention on Human Rights and reiterated in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. It should be pointed out that, under Article 6 of the latter Convention, personal data concerning health constitute a special category of data and are as such subject to special rules.

64. However, certain restrictions to the respect of privacy are possible for one of the reasons and under the conditions provided for in under Article 26.1. For example, a judicial authority may order that a test be carried out in order to identify the author of a crime (exception based on the prevention of a crime) or to determine the filiation link (exception based on the protection of the rights of others).

65. The first sentence of the second paragraph lays down that individuals are entitled to know any information collected about their health, if they wish to know. This right is of fundamental

importance in itself but also conditions the effective exercise of other rights such as the right of consent set forth in Article 5.

66. A person's "right to know" encompasses all information collected about his or her health, whether it be a diagnosis, prognosis or any other relevant fact.

67. The right to know goes hand in hand with the "right not to know", which is provided for in the second sentence of the second paragraph. Patients may have their own reasons for not wishing to know about certain aspects of their health. A wish of this kind must be observed. The patient's exercise of the right not to know this or that fact concerning his health is not regarded as an impediment to the validity of his consent to an intervention; for example, he can validly consent to the removal of a cyst despite not wishing to know its nature.

68. In some circumstances, the right to know or not to know may be restricted in the patient's own interest or else on the basis of Article 26.1, for example, in order to protect the rights of a third party or of society.

69. Therefore, the last paragraph of Article 10 sets out that in exceptional cases domestic law may place restrictions on the right to know or not to know in the interests of the patient's health (for example a prognosis of death which might, in certain cases if immediately passed on to the patient, seriously worsen his or her condition). In some cases, the doctor's duty to provide information which is also covered under Article 4 conflicts with the interests of the patient's health. It is for domestic law, taking account of the social and cultural background, to solve this conflict. Where appropriate under judicial control, domestic law may justify the doctor sometimes withholding part of the information or, at all events, disclosing it with circumspection ("therapeutic necessity").

70. Furthermore, it may be of vital importance for patients to know certain facts about their health, even though they have expressed the wish not to know them. For example, the knowledge that they have a predisposition to a disease might be the only way to enable them to take potentially effective (preventive) measures. In this case, a doctor's duty to provide care, as laid down in Article 4, might conflict with the patient's right not to know. It could also be appropriate to inform an individual that he or she has a particular condition when there is a risk not only to that person but also to others. Here too it will be for domestic law to indicate whether the doctor, in the light of the circumstances of the particular case, may make an exception to the right not to know. At the same time, certain facts concerning the health of a person who has expressed a wish not to be told about them may be of special interest to a third party, as in the case of a disease or a particular condition transmissible to others, for example. In such a case, the possibility for prevention of the risk to the third party might, on the basis of Article 26, warrant his or her right taking precedence over the patient's right to privacy, as laid down in paragraph 1, and as a result the right not to know, as laid down in paragraph 2. In any case, the right not to know of the person concerned may be opposed to the interest to be informed of another person and the interests of these two persons should be balanced by internal law.

#### **Chapter IV – Human genome**

71. Genetic science has undergone dramatic changes in recent years. In human medicine, apart from the pharmaceutical field, there are other areas in which, it can be applied, namely: genetic testing, gene therapy and the scientific elucidation of disease causes and mechanisms.

72. Genetic testing consists of medical examinations aimed at detecting or ruling out the presence of hereditary illnesses or predisposition to such illnesses in a person by directly or indirectly analysing their genetic heritage (chromosomes, genes).

73. The aim of gene therapy is to correct changes to the human genetic heritage which may result in hereditary diseases. The difference between gene therapy and the analysis of the genome lies in the fact that the latter does not modify the genetic heritage but simply studies its structure and its relationship with the symptoms of the illness. In theory, there are two distinct forms of gene therapy. Somatic gene therapy aims to correct the genetic defects in the somatic

cells and to produce an effect restricted to the person treated. Were it possible to undertake gene therapy on germ cells, the disease of the person who has provided the cells would not be cured, as the correction would be carried out on the cells whose sole function is to transmit genetic information to future generations.

#### **Article 11 – Non-discrimination**

74. The mapping out of the human genome, which is advancing rapidly, as well as the development of the genetic tests which are linked with it are likely to bring substantial advances in the prevention of illnesses and the administration of treatment. But genetic testing also raises considerable concerns. Among these the most widespread is probably the concern that genetic testing, which can detect a genetic disease, a predisposition or a susceptibility to a genetic disease, may become a means of selection and discrimination.

75. The fundamental principle established in Article 11 is that any form of discrimination against an individual on grounds of his or her genetic heritage is prohibited.

76. Under Article 14 of the European Convention on Human Rights, the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status. Article 11 adds to this list a person's genetic heritage. The prohibition of discrimination set out thus applies to all areas included in the field of application of this Convention. This notion also includes non-discrimination on grounds of race as understood by the 1965 United Nations Convention on the Elimination of all Forms of Racial Discrimination and as it has been interpreted by the Convention Committee (CERD).

77. Whereas the term "discrimination" has usually a negative connotation in French, this is not necessarily the case in English (where one must use the expression "unfair discrimination"); it has, however, been decided to keep the same term in both languages, as it is in the European Convention of Human Rights and in the case law of the Court. Discrimination here must, therefore, in French as in English, be understood as unfair discrimination. In particular, it cannot prohibit positive measures which may be implemented with the aim of re-establishing a certain balance in favour of those at a disadvantage because of their genetic inheritance.

#### **Article 12 – Predictive genetic tests**

78. Progress in the study of human genetics has occurred at a remarkable rate over the course of the last ten years. Developments in the field now make it possible to identify with much greater precision than ever before those who carry specific genes for major single gene disorders (for example cystic fibrosis, haemophilia, Huntington's disease, retinitis pigmentosa etc) and also those who carry genes which may increase their risk of developing major disorders later in life (for example heart disease, cancer and Alzheimer's disease). It has been possible to identify those who were destined or likely to develop certain single gene disorders on the basis of a clear mendelian pattern of inheritance or through the identification of phenotypic characteristics (either through clinical observation or through standard laboratory biochemical tests) which permit action to be taken to prevent the onset of clinical disease. Advances in genetics have led to much more sophisticated and precise techniques for testing for some disorders. However, the identification of a particular abnormal gene does not necessarily imply that the carrier will develop the disease nor does it predict the pattern or severity of the disease.

79. Modern techniques have also made it possible to identify genes which contribute to the development of major disorders later in life – and to which other genes and environmental and lifestyle factors also made a contribution. It has also been possible to identify some of these genetically determined risk factors in the past through the identification of phenotypic characteristics. The probability of individuals developing the disease later in life is, however, much less certain than in the case of the single gene disorders, since the probability of doing so depends upon factors which are outside individuals' control (for example other genetic

characteristics) as well as factors which may be modified by individuals in ways which will alter the risk (for example diet, smoking, lifestyle factors etc).

80. Tests which are predictive of certain genetic diseases may offer considerable benefits to an individual's health by allowing timely preventive treatment to be instituted or by offering opportunities to diminish the risks through modifications in behaviour, lifestyle or environment. This, however, is not possible at present in many genetically determined disorders. The right to know as well as the right not to know and proper informed consent are, therefore, of particular importance in this field since problems may clearly arise for the individual resulting from tests predictive of genetic disease for which there is currently no effective treatment.

A further complicating factor is that tests predictive of genetically determined diseases may also have implications for members of the family and the offspring of the person who has undergone testing. It is essential that appropriate professional standards are developed in this field.

81. The situation is even more complicated with predictive testing for serious late onset diseases, when there is at present no treatment available. Screening for serious late onset diseases should remain exceptional, even when screening is related to scientific research: it would put too much strain on the free participation and on the privacy of individuals.

82. Because of the particular problems which are related to predictive testing, it is necessary to strictly limit its applicability to health purposes for the individual. Scientific research likewise should be carried out in the context of developing medical treatment and enhancing our ability to prevent disease.

83. Article 12 as such does not imply any limitation of the right to carry out diagnostic interventions at the embryonic stage to find out whether an embryo carries hereditary traits that will lead to serious diseases in the future child.

84. Because there is an apparent risk that use is made of genetic testing possibilities outside health care (for instance in the case of medical examination prior to an employment or insurance contract), it is of importance to clearly distinguish between health care purposes for the benefit of the individual on the one hand and third parties' interests, which may be commercial, on the other hand.

85. Article 12 prohibits the carrying out of predictive tests for reasons other than health or health-related research, even with the assent of the person concerned. Therefore, it is forbidden to do predictive genetic testing as part of pre-employment medical examinations, whenever it does not serve a health purpose of the individual. This means that in particular circumstances, when the working environment could have prejudicial consequences on the health of an individual because of a genetic predisposition, predictive genetic testing may be offered without prejudice to the aim of improving working conditions. The test should be clearly used in the interest of the individual's health. The right not to know should also be respected.

86. Insofar as predictive genetic testing, in the case of employment or private insurance contracts, does not have a health purpose, it entails a disproportionate interference in the rights of the individual to privacy. An insurance company will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will it be able to refuse the conclusion or modification of such a policy on the ground that the applicant has not submitted to a test, as the conclusion of a policy cannot reasonably be made conditional on the performance of an illegal act.

87. However, national law may allow for the performance of a test predictive of a genetic disease outside the health field for one of the reasons and under the conditions provided for in Article 26.1 of the Convention.

88. According to Article 5, a genetic test may only be carried out after the person concerned has given free and informed consent. Article 12 adds a supplementary condition which is that predictive tests must be accompanied by appropriate genetic counselling.

**Article 13 – Interventions on the human genome** See the [Addendum](#)

89. The progress of science, in particular in knowledge of the human genome and its application, has raised very positive perspectives, but also questions and even great fears. Whilst developments in this field may lead to great benefit for humanity, misuse of these developments may endanger not only the individual but the species itself. The ultimate fear is of intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities. In Article 13, the Convention provides the answer to these fears in several ways.

90. In every case, any intervention which aims to modify the human genome must be carried out for preventive, diagnostic or therapeutic purposes. Interventions aimed at modifying genetic characteristics not related to a disease or to an ailment are prohibited. As long as somatic cell gene therapy is currently at the research stage, its application can be allowed only if it complies with the standards of protection provided for in Article 15 and the following Articles.

91. Interventions seeking to introduce any modification in the genome of any descendants are prohibited. Consequently, in particular genetic modifications of spermatozoa or ova for fertilisation are not allowed. Medical research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation is only permissible if carried out *in vitro* with the approval of the appropriate ethical or regulatory body.

92. On the other hand the article does not rule out interventions for a somatic purpose which might have unwanted side-effects on the germ cell line. Such may be the case, for example, for certain treatments of cancer by radiotherapy or chemotherapy, which may affect the reproductive system of the person undergoing the treatment.

**Article 14 – Non-selection of sex**

93. Medically-assisted procreation includes artificial insemination, *in vitro* fertilisation and any technique having the same effect which permits procreation beyond the natural process. According to this Article, it is not permissible to use a technique of medically-assisted procreation in order to choose a future child's sex, except where serious hereditary sex-related disease is to be avoided.

94. It is for internal law to determine, according to the procedures applied in each state, the seriousness of a hereditary sex-related disease. In some countries, guidelines are laid down by political or administrative authorities or by national ethics committees, *ad hoc* committees, professional bodies, etc. In every case, appropriate genetic counselling of the persons concerned is necessary.

**Chapter V – Scientific research**

**Article 15 – General rule**

95. Freedom of scientific research in the field of biology and medicine is justified not only by humanity's right to knowledge, but also by the considerable progress its results may bring in terms of the health and well-being of patients.

96. Nevertheless, such freedom is not absolute. In medical research it is limited by the fundamental rights of individuals expressed, in particular, by the provisions of the Convention and by other legal provisions which protect the human being. In this connection, it should be pointed out that the first Article of the Convention specifies that its aim is to protect the dignity and identity of human being and guarantee to everyone, without discrimination, respect for their integrity as well as for other rights and fundamental freedoms. Any research will therefore have to observe these principles.

## **Article 16 – Protection of persons undergoing research**

97. This Article lays down the conditions for all research on human beings. These conditions were largely inspired by Recommendation No. R (90) 3 of the Committee of Ministers to member States on medical research on the human being.

98. The first condition is that there must be no alternative of comparable effectiveness to research on humans. Consequently, research will not be allowed if comparable results can be obtained by other means. Invasive methods will not be authorised if other less invasive or non-invasive methods can be used with comparable effect.

99. The second condition is that the risks which may be incurred by that person are not disproportionate to the potential benefits of the research.

100. The third condition is the need for an independent examination of the scientific merit as well as of the ethical, including legal, social and economic acceptability of the research project. The examination of the latter aspects have to be carried out by independent multi-disciplinary ethics committees.

101. Paragraph iv underlines the obligation to inform the person in advance of their legal rights and guarantees, for example their right to freely withdraw their consent at any time.

102. Paragraph v reinforces conditions set forth in Article 5 concerning consent. In the sphere of research, implicit consent is insufficient. For this reason the Article requires not only the person's free and informed consent, but their express, specific and written consent. The words "specific consent" are to be understood here as meaning consent which is given to one particular intervention carried out in the framework of research.

## **Article 17 – Protection of persons not able to consent to research**

### *Paragraph 1*

103. In its first paragraph this Article establishes a principle with regard to research on a person who is not able to consent: the research must be potentially beneficial to the health of the person concerned. The benefit must be real and follow from the potential results of the research, and the risk must not be disproportionate to the potential benefit.

104. Moreover, to allow such research, there should be no alternative subject with full capacity. It is not sufficient that there should be no capable volunteers. Recourse to research on persons not able to consent must be, scientifically, the sole possibility. This will apply, for instance, to research aimed at improving the understanding of development in children or improving the understanding of diseases affecting these people specifically, such as infant diseases or certain psychiatric disorders such as dementia in adults. Such research can only be carried out, respectively, on children or the adults concerned.

105. Protection of the person not able to consent is also strengthened by the requirement that the necessary authorisation as provided for under Article 6 be given specifically and in writing. It is also stipulated that such authorisation may be freely withdrawn at any time.

106. The research must not be carried out if the person concerned objects. In the case of infants or very young children, it is necessary to evaluate their attitude taking account of their age and maturity. The rule prohibiting the carrying out of the research against the wish of the subject reflects concern, in research, for the autonomy and dignity of the person in all circumstances, even if the person is considered legally incapable of giving consent. This provision is also a means of guaranteeing that the burden of the research is acceptable to the person at all times.

*Paragraph 2*

107. Under the protective conditions prescribed by domestic law, paragraph 2 provides, exceptionally, for the possibility of waiving the direct benefit rule on certain very strict conditions. Were such research to be banned altogether, progress in the battles to maintain and improve health and to combat diseases only afflicting children, mentally disabled persons or persons suffering from senile dementia would become impossible. The group of people concerned may in the end benefit from this kind of research.

108. As well as the general conditions of research on persons not able to consent, a certain number of supplementary conditions must be fulfilled. In this way the Convention enables these people to enjoy the benefits of science in the fight against disease, while guaranteeing the individual protection of the person who undergoes the research. The required conditions imply that:

- in order to obtain the necessary results for the patient group concerned, there is neither an alternative method of comparable effectiveness to research on humans, nor research of comparable effectiveness on individuals capable of giving informed consent;
- the research has the aim of contributing to the ultimate attainment of results capable of conferring a benefit to the person concerned or to other persons in the same age category, or afflicted with the same disease or disorder or having the same condition, through significant improvements in the scientific understanding of the individual's conditions, disease or disorder;
- the research entails only minimal risk and minimal burden for the individual concerned (for example blood sampling – see paragraphs 111 and 113 below);
- the research project not only has scientific merit but is also ethically and legally acceptable and has been given prior approval by the competent bodies;
- the person's representative or an authority or a person or body provided for by law has given authorisation (adequate representation of the interests of the patient);
- the person concerned does not object (the wish of the person concerned prevails and is always decisive);
- authorisation for this research may be withdrawn at any time throughout a research project.

109. One of the first supplementary conditions is that this research should be likely to significantly improve the scientific understanding of a person's health condition, disease or disorder and obtain, in the end, results benefitting the health of the person undergoing research or the health of persons in the same category. This means, for example, that a minor may participate in research on an ailment from which he or she suffers even if the minor would not benefit by the results of the research, provided that the research might be of significant benefit to other children suffering from the same disease. In the case of healthy minors undergoing research it is obvious that the result of the research might be of benefit only to other children. In cases where healthy minors participate in research, clearly it is to obtain results of benefit to other children; however such research may well be of ultimate benefit to healthy children taking part in this research.

110. The research on "the individual's condition" might cover, with regard to research on children, not only diseases or abnormalities peculiar to childhood or certain aspects of common diseases that are specific to childhood, but also the normal development of the child where knowledge is necessary for the understanding of these diseases or abnormalities.



111. While Article 16.ii restricts research in general by establishing a criterion of risk/benefit proportionality, Article 17 lays down a more stringent requirement for research without direct benefit to persons incapable of giving consent, namely only minimal risk and minimal burden for the individual concerned. Indeed, it is only in respecting these conditions that such research may be carried out without constituting an instrumentalisation of these persons contrary to their dignity. For example, taking a single blood sample from a child would generally only present a minimal risk, and might therefore be regarded as acceptable.

112. Diagnostic and therapeutic progress for the benefit of sick children depends to a large extent on new knowledge and insight regarding the normal biology of the human organism and calls for research on the age-related functions and development of normal children before it can be applied in the treatment of sick children. Moreover, paediatric research concerns not only the diagnosis and treatment of serious pathological conditions but also the maintenance and improvement of the state of health of children who are not ill, or who are only slightly ill. In this connection mention should be made of prophylaxis through vaccination or immunisation, dietary measures or preventive treatments whose effectiveness, especially in terms of costs and possible risks, urgently requires evaluation by means of scientifically controlled studies. Any restriction based on the requirement of "potential direct benefit" for the person undergoing the test would make such studies impossible in the future.

113. As examples, the following fields of research can be mentioned, provided all conditions outlined above are met (including the condition that it is impossible to obtain the same results through research carried out on capable persons and the condition of minimal risk and minimal burden):

- in respect of children : replacing X-ray examinations or invasive diagnostic measures for children by ultrasonic scanning; analyses of incidental blood samples from newborn infants without respiratory problems in order to establish the necessary oxygen content for premature infants; discovering the causes and improving treatment of leukaemia in children (for example by taking a blood sample);

- in respect of adults not able to consent: research on patients in intensive care or in a coma to improve the understanding of the causes of coma or the treatment in intensive care.

114. The above-mentioned examples of medical research cannot be described as routine treatment. They are in principle without direct therapeutic benefit for the patient. However, they may be ethically acceptable if the above highly protective conditions, resulting from the combined effect of Articles 6, 7, 16 and 17, are fulfilled.

#### **Article 18 – Research on embryos in vitro**

115. The first paragraph of Article 18 stresses the necessity to protect the embryo in the framework of research: where national law allows research on embryos *in vitro* the law must ensure adequate protection of the embryo.

116. The article does not take a stand on the admissibility of the principle of research on *in vitro* embryos. However, paragraph 2 of the Article prohibits the creation of human embryos with the aim to carry out research on them.

### **Chapter VI – Organ and tissue removal from living donors for transplantation purposes**

#### **Article 19 – General rule**

117. Organ transplants are current medical techniques helping to save, prolong or greatly facilitate the lives of persons suffering from certain serious disorders. The purpose of this chapter is to establish a framework to protect living donors in the context of organ (in particular

liver, kidney, lung, pancreas) or tissue removal (for instance, skin). The provisions in this chapter do not apply to blood transfusions.

118. According to the first principle of the text, organs or tissues should be removed from deceased donors rather than from living donors whenever possible.

Removing organs or tissue from living donors always represents a risk for the donors, if only because of the anaesthesia they sometimes have to undergo. This implies that organs from living persons should not be used where an appropriate organ from a deceased person is available.

119. The second condition in the case of living donors is that there exists no alternative therapeutic method of comparable effectiveness. In view of the risk involved in any organ removal, there is no justification for resorting to this if there is another way of bringing the same benefit to the recipient. The transplant must therefore be necessary in the sense that there is no other solution that would produce similar results, such as "conventional" treatment, or tissues of animal origin, cultured tissues or tissues transplanted from the recipient. In this respect dialysis treatment is not considered to provide results in terms of the patient's quality of life comparable with those obtained by a kidney transplant.

120. In order for an organ to be removed, the express and specific consent of the donor must be given, in accordance with Article 5 of the Convention. Moreover, Article 19, paragraph 2, stipulates that this consent must be specific and given in written form or before an official body, making the conditions set forth in Article 5 more stringent for this particular type of intervention. The official body concerned could be a court or a notary, for example.

121. The removal of organs may only be carried out for the therapeutic benefit of the recipient where the need was known before the removal. Tissue, for its part, can be stored in tissue banks for future needs (it should be stressed that this concerns, in most cases, unused tissue – for example tissue removed after an intervention – see Article 22); in this case the provisions of Recommendation No. R (94) 1 of the Committee of Ministers to the member States on human tissue banks are applicable.

#### **Article 20 – Protection of persons not able to consent to organ removal**

122. Article 20 deals specifically with the question of the removal of organs or tissue from persons incapable of giving consent. The principle is that this practice is prohibited.

123. Only in very exceptional circumstances may exceptions be made to this rule, and only for the removal of regenerative tissue. Within the meaning of this Article, regenerative tissue is that capable of reconstituting its tissue mass and function after partial removal. These exceptions are justified by the fact that regenerative tissue, in particular bone marrow, can only be transplanted between genetically compatible persons, often brothers and sisters.

124. If, at the present time, bone marrow transplants among brothers and sisters is the most important situation which meets with the condition of this article, the formula "regenerative tissue" takes into account future developments in medicine.

125. Paragraph 2 therefore permits removal of bone marrow from a minor for the benefit of his or her brother or sister. It is the principle of mutual aid between very close members of a family which, subject to certain conditions, can justify an exception to the prohibition of removal which is intended to protect the persons who are not able to give their consent. This exception to the general rule is qualified by a number of conditions set forth in Article 20, designed to protect the person who is incapable of giving consent, and these may be supplemented by national law. The conditions of Article 19, paragraph 1, also apply.

126. The first condition is the absence, within reasonable limits, of a compatible donor who is able to consent.

127. Moreover, the removal is only authorised on the condition that, in the absence of the donation, the life of the recipient is in danger. It goes without saying that the risks to the donor should be acceptable; the professional standards of Article 4 naturally apply, in particular as regards the balance between risk and benefit.

128. It is also required that the beneficiary be a brother or sister. This restriction is intended to avoid both family and doctors going to extreme lengths to find a donor at any price, even if the level of kinship is distant and the chances for a successful transplant are not very likely, because of tissue incompatibility.

129. Furthermore, in keeping with Article 6, the authorisation of the representative of the person not able to consent or the authorisation of the authority or body provided for by law is needed before the removal can be carried out (see under 38 above for withdrawal). The agreement of the competent body mentioned in Article 20, iv is also required. The intervention of such a body (which might be a court, a professionally qualified body, an ethics committee, etc.) aims to guarantee that the decision to be taken is impartial.

130. Finally, the removal may not be carried out if the potential donor objects in any way. As in the case of research, this opposition, in whatever form, is decisive and must always be observed.

## **Chapter VII – Prohibition of financial gain and disposal of a part of the human body**

### **Article 21 – Prohibition of financial gain**

131. This article applies the principle of human dignity set forth in the preamble and in Article 1.

132. It states in particular that the human body and its parts must not, as such, give rise to financial gain. Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital. However, technical acts (sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport, etc.) which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this Article does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such. Further, this Article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalisation).

133. The provision does not refer to such products as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity.

134. The question of patents was not considered in connection with this provision; accordingly the latter was not intended to apply to the question of the patentability of biotechnological inventions. Such was the complexity of the problem of patents that a detailed study was necessary before any regulations were drawn up. If such a study led to the conclusion that regulations on the subject were desirable, the regulations should include principles and rules suited to the specific nature of the subject. In this respect, it has been noted that the European Community has issued a proposal for a Directive containing the principle according to which "the human body and its elements in their natural state shall not be considered patentable inventions".

### **Article 22 – Disposal of a removed part of the human body**

135. Parts of the human body are often removed in the course of interventions, for example surgery. The aim of this article is to ensure the protection of individuals with regard to parts of their body which are thus removed and then stored or used for a purpose different from that for

which they have been removed. Such a provision is necessary in particular, because much information on the individual may be derived from any part of the body, however small (for example blood, hair, bone, skin, organ). Even when the sample is anonymous the analysis may yield information about identity.

136. This provision thus establishes a rule consistent with the general principle in Article 5 on consent, ie that parts of the body which have been removed during an intervention for a specified purpose must not be stored or used for a different purpose unless the relevant conditions governing information and consent have been observed.

137. The information and consent arrangements may vary according to the circumstances, thus allowing for flexibility since the express consent of an individual to the use of parts of his body is not systematically needed. Thus, sometimes, it will not be possible, or very difficult, to find the persons concerned again in order to ask for their consent. In some cases, it will be sufficient for a patient or his or her representative, who have been duly informed (for instance, by means of leaflets handed to the persons concerned at the hospital), not to express their opposition. In other cases, depending on the nature of the use to which the removed parts are to be put, express and specific consent will be necessary, in particular where sensitive information is collected about identifiable individuals.

138. This article must not be understood to authorise an exception to the principle in Article 19 that removal of organs for transplantation purposes may be carried out only for the benefit of the recipient. However, in a case where the organ appears not to be suitable for transplantation purposes, because of its condition, it may then exceptionally be used for research in transplantation medicine specifically related to the particular organ.

## **Chapter VIII – Infringements of the provisions of the Convention**

### **Article 23 – Infringement of the rights or principles**

139. This article requires the Parties to make available a judicial procedure to prevent or put a stop to an infringement of the principles set forth in the Convention. It therefore covers not only infringements which have already begun and are ongoing but also the threat of an infringement.

140. The judicial protection requested must be appropriate and proportionate to the infringement or the threats of infringement of the principles. Such is the case, for example, with proceedings initiated by a public prosecutor in cases of infringements affecting several persons unable to defend themselves, in order to put an end to the violation of their rights.

141. Under the Convention, the appropriate protective machinery must be capable of operating rapidly as it has to allow an infringement to be prevented or halted at short notice. This requirement can be explained by the fact that, in many cases, the very integrity of an individual has to be protected and an infringement of this right might have irreversible consequences.

142. The judicial protection thus provided by the Convention applies only to unlawful infringements or to threats thereof.

The reason for this qualifying adjective is that the Convention itself, in Article 26.1, permits restrictions to the free exercise of the rights it recognises.

### **Article 24 – Compensation for undue damage**

143. This Article sets forth the principle that any person who has suffered undue damage resulting from an intervention is entitled to fair compensation. The Convention uses the expression "undue damage" because in medicine some damage, such as amputation, is inherent in the therapeutic intervention itself.

144. The due or undue nature of the damage will have to be determined in the light of the circumstances of each case. The cause of the damage must be an intervention in the widest sense, taking the form of either an act or an omission. The intervention may or may not constitute an offence. In order to give entitlement to compensation, the damage must result from the intervention.

145. Compensation conditions and procedures are prescribed by national law. In many cases, this establishes a system of individual liability based either on fault or on the notion of risk or strict liability. In other cases, the law may provide for a collective system of compensation irrespective of individual liability.

146. On the subject of fair compensation, reference can be made to Article 50 of the European Convention on Human Rights, which allows the Court to afford just satisfaction to the injured party.

### **Article 25 – Sanctions**

147. Since the aim of the sanctions provided for in Article 25 is to guarantee compliance with the provisions of the Convention, they must be in keeping with certain criteria, particularly those of necessity and proportionality. As a result, in order to measure the expediency and determine the nature and scope of the sanction, the domestic law must pay special attention to the content and importance of the provision to be complied with, the seriousness of the offence and the extent of its possible repercussions for the individual and for society.

## **Chapter IX – Relation between this Convention and other provisions**

### **Article 26 – Restrictions on the exercise of rights**

#### *Paragraph 1*

148. This article lists the only possible exceptions to the rights and protective provisions contained in all the provisions of the Convention, without prejudice to any specific restrictions which this or that Article may involve.

149. It echoes partially the provisions of Article 8, paragraph 2, of the European Convention on Human Rights. The exceptions made in Article 8, paragraph 2, of the European Convention on Human Rights have not all been considered relevant to this Convention. The exceptions defined in the article are aimed at protecting collective interests (public safety, the prevention of crime, and the protection of public health) or the rights or freedoms of others.

150. Compulsory isolation of a patient with a serious infectious disease, where necessary, is a typical example of an exception for reason of the protection of public health.

151. A person who may, due to his or her mental disorder, be a possible source of serious harm to others may, according to the law, be subjected to a measure of confinement or treatment without his or her consent. Here, in addition to the cases contemplated in Article 7, the restriction may be applicable in order to protect other people's rights and freedom.

152. Protection of the rights of others may also, for example, justify an order by a judicial authority for a test to be carried out to establish parentage.

153. It may also be justified to use genetic assessments (DNA tests) for the identification of persons in connection with criminal investigation.

154. Certain legislations provide for court-ordered psychiatric treatment of an accused person who, failing such treatment, would be unfit to stand trial, with the object of enabling the accused to make a proper defence. Such court-ordered treatment, with attached appropriate safeguards, may be considered as relevant within the scope of Article 26, which refers namely

to necessary measures for the fair administration of justice ("prevention of crime") which, in a democratic society, include the defence of the accused.

155. The protection of the patient's health is not mentioned in this paragraph as one of the factors justifying an exception to the provisions of the Convention as a whole. In order to clarify its scope, it seemed preferable to define this exception in each of the provisions expressly alluding to it. Article 7, for example, specifies the conditions on which individuals suffering from mental disorders may, without their consent, be given treatment if their health might seriously suffer otherwise.

156. Moreover, defending the economic well-being of the country, public order or morals and national security are not included amongst the general exceptions referred to in the first paragraph of this article, unlike Article 8 of the European Convention on Human Rights. It did not appear desirable, in the context of this Convention, to make the exercise of fundamental rights chiefly concerned with the protection of a person's rights in the health sphere subject to the economic well-being of the country, to public order, to morals or to national security.

157. The economic aspect is however referred to in Article 3 by the words "available resources"; however, within the meaning of this article this notion does not represent a reason for allowing for an exception to the rights secured in other provisions of the Convention.

158. War and armed conflict were also ruled out as possible grounds for exceptions. However, this is not meant as preventing the law from taking specific measures in the military aiming at protecting public health in that particular context.

159. The reasons mentioned in Article 26.1 should not be regarded as justifying an absolute exception to the rights secured by the Convention. To be admissible, restrictions must be prescribed by law and be necessary in a democratic society for the protection of the collective interest in question or for the protection of individual interests, that is the rights and freedom of others. These conditions must be interpreted in the light of the criteria established with regard to the same concepts by the case-law of the European Court of Human Rights. In particular, the restrictions must meet the criteria of necessity, proportionality and subsidiarity, taking into account the social and cultural conditions proper to each State. The term "prescribed by law" should be interpreted in accordance with the meaning usually given to it by the European Court of Human Rights, that is a formal law is not required and each State may adopt the form of domestic law it considers most appropriate.

#### *Paragraph 2*

160. The restrictions set out in the first paragraph of the Article shall not apply to the provisions mentioned in the second paragraph. It concerns the following provisions: Article 11 (Non-discrimination), Article 13 (Interventions on human genome), Article 14 (Non selection of sex), Article 16 (Protection of persons undergoing research), Article 17 (Protection of persons not able to consent to research), Articles 19 and 20 (Organ and tissue removal from living donors for transplantation purposes) and Article 21 (Prohibition of financial gain).

#### **Article 27 – Wider protection**

161. In pursuance of this article, the Parties may apply rules of a more protective nature than those contained in the Convention. In other words, the text lays down common standards with which States must comply, while allowing them to provide greater protection of the human being and of human rights with regard to applications of biology and medicine.

162. A conflict may arise between the various rights established by the Convention, for example between a scientist's right of freedom of research and the rights of a person submitting to the research. However, the expression "wider protection" must be interpreted in the light of the purpose of the Convention, as defined in Article 1, namely the protection of the human being with regard to the application of biology and medicine.

In the example quoted, any additional statutory protection can only mean greater protection for a person submitting to research.

## **Chapter X – Public debate**

### **Article 28 – Public debate**

163. The purpose of this article is to prompt the Parties to create greater public awareness of the fundamental questions raised by the application of biology and medicine. Society's views must be ascertained as far as possible with regard to problems concerning its members as a whole. To this end, appropriate public discussion and consultation are recommended. The word "appropriate" leaves the Parties free to select the most suitable procedures. Where appropriate, for example, States may organise ethics committees and have recourse to the teaching of ethics in the field of medicine, biology and health to health care professionals, teachers and the general public.

## **Chapter XI – Interpretation and follow-up of the Convention**

### **Article 29 – Interpretation of the Convention**

164. This article allows the possibility of requesting the European Court of Human Rights' advisory opinion on legal questions concerning the interpretation of the Convention. The opinion shall be without direct reference to any specific proceedings in a court.

165. This Convention does not itself give individuals a right to bring proceedings before the European Court of Human Rights. However, facts which are an infringement of the rights contained in this Convention may be considered in proceedings under the European Convention of Human Rights, if they also constitute a violation of one of the rights contained in the latter Convention.

### **Article 30 (Reports on the application of the Convention)**

166. According to the model of Article 57 of the European Convention of Human Rights, this Article stipulates that any Party, on the request of the Secretary General of the Council of Europe, shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

## **Chapter XII – Protocols**

### **Article 31 – Protocols**

167. The Convention establishes principles valid for all applications of biology and medicine in human beings. This article makes provision for the immediate drawing up of protocols containing rules on specific fields. As the purpose of the protocols is to develop further the principles contained in the Convention, their provisions should not depart from those therein. In particular, they cannot lay down rules affording human beings less protection than that resulting from the principles of the Convention.

168. To be able to sign or ratify a protocol, a State must have simultaneously or previously signed or ratified the Convention. On the other hand, States which have signed or ratified the Convention will not be obliged to sign or ratify a protocol.

## **Chapter XIII – Amendments to the Convention**

### **Article 32 – Amendments to the Convention**

169. Amendments to the Convention shall be examined by the CDBI, or by any other committee designated by the Committee of Ministers. Accordingly, each member State of the Council of Europe, as well as each Party to the Convention which is not a member of the Council of Europe, will have the right to vote concerning the proposed amendments.

170. This article provides that the Convention shall be re-examined no later than five years from its entry into force and thereafter at such intervals as the Committee in charge of the re-examination may determine.

## **Chapter XIV – Final clauses**

### **Article 33 – Signature, ratification and entry into force**

171. Other than the member States of the Council of Europe, the following States, which took part in its preparation, may sign the Convention: Australia, Canada, the Holy See, Japan and the United States of America.

### **Article 35 – Territories**

172. Since this provision is mainly aimed at overseas territories, it was agreed that it would be clearly against the philosophy of the Convention for any Party to exclude parts of its main territory from the application of this instrument, and that there would be no need to lay this down explicitly in the Convention.

### **Article 36 – Reservations**

173. This article, on the model of Article 64 of the European Convention of Human Rights, permits reservations in respect of any particular provision of the Convention, to the extent that any law in force is not in conformity with the provision.

174. The term law does not imply that a formal law is required (for example, in some countries, the professional bodies issue their own deontological rules which are applicable to their members to the extent that they do not contradict State norms). However, according to paragraph 1, a reservation of a general character, that is couched in terms too vague or broad for it to be possible to determine its exact meaning and scope, is not permitted.

175. Furthermore, according to paragraph 2, any reservation made shall contain a brief statement of the law concerned; this statement constitutes an evidential factor and contributes to legal certainty, and is not a purely formal requirement but a condition of substance (see European Court of Human Rights, *Belilos Case*, sections 55 and 59).

176. It was agreed that any declaration, even described as interpretative, made by the State or the European Community relating to any provision of the Convention, which seeks to modify for the declaring State the obligations deriving from such provision should meet, in order to be valid, the requirements set out in Article 36.



## ADDENDUM

### **Conclusions of the re-examination process of Article 13 of the Convention on Human rights and Biomedicine**

*In accordance with Article 32 of the Convention on Human Rights and Biomedicine (Oviedo Convention), the Committee on Bioethics (DH-BIO) proceeded to the re-examination of Article 13 of the Oviedo Convention. During its 1st plenary meeting, the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) [1] adopted the conclusions hereafter, which were transmitted for information to the Committee of Ministers in Appendix II of the abridged report of the plenary meeting.*

1. In accordance with Article 32 of the Convention on Human rights and Biomedicine (Oviedo Convention), and as foreseen in the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020 – 2025), the DH-BIO proceeded with the re-examination of Article 13 of the Oviedo Convention.

2. Following the discussion held and on the basis of the comments made by delegations, the DH-BIO concluded that, taking into account the technical and scientific aspects of these developments as well as the ethical issues they raise, it considered that the conditions were not met for a modification of the provisions of Article 13. However, it agreed on the need to provide clarifications, in particular on the terms “preventive, diagnostic and therapeutic” and to avoid misinterpretation of the applicability of this provision to “research”.

3. The DH-BIO entrusted a Drafting Group with the task of preparing those clarifications in close cooperation with the Secretariat. They were discussed by the CDBIO at its 1st meeting, which considered that the clarifications that appear in appendix to these conclusions could usefully complement the explanatory report on the Convention drawn under the authority of the Secretary General of the Council of Europe.

### **Appendix – Clarifications as agreed by the CDBIO in the light of the acquainted experience in the implementation of the Oviedo Convention**

In keeping with Article 32 of the Oviedo Convention and as foreseen in the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020 – 2025), the DH-BIO, and later the CDBIO, began re-examining Article 13 of the Oviedo Convention in November 2020. The provision of Article 13 was discussed, and the following clarifications agreed in the light of the experience gained from implementing the provision.

#### Scope with regard to research

- The provisions of Article 13 apply to any intervention seeking to modify the human genome. This includes interventions carried out in research as well as in a clinical context.
- If an intervention seeking to modify the human genome is carried out on an individual or on cells that are to be introduced into an individual in a research context, the standards laid down for the protection of research participants in Article 15 and the following Articles must be respected.
- The prohibition of an intervention seeking to introduce a modification in the genome of any descendants has the implication that gametes, embryos or their precursors that have been subjected to such intervention may not be used for the purposes of procreation.
- The requirement in paragraph 91 of the Explanatory Report, for approval by the appropriate ethical or regulatory body for research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation, applies equally to such research on embryos, gametes and their precursors.

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<sup>1</sup> By decision of the Committee of Ministers, starting on 1<sup>st</sup> January 2022, the DH-BIO was replaced by the CDBIO, which ensures the responsibility assigned by Art. 32 of the Oviedo Convention.

Preventive, diagnostic or therapeutic purposes

- The Article limits the purposes for which any intervention that seeks to modify the human genome may be carried out, to preventive, diagnostic and therapeutic purposes.
- An intervention seeking to modify the human genome undertaken for a preventive purpose, will aim at avoiding the occurrence of a disease or disorder. Disease and disorder (also referred to as “ailment” in paragraph 90 of the Explanatory Report), are defined in accordance with internationally accepted medical standards. An example of such medical standards is provided by the World Health Organisation’s International Statistical Classification of Diseases and related Health Problems (ICD).
- An intervention seeking to modify the human genome undertaken for diagnostic purpose, will aim at identifying a disease or disorder, or a genetic variant/factor associated with the development of a disease or disorder as defined above.
- An intervention seeking to modify the human genome undertaken for a therapeutic purpose, will aim at controlling symptoms of a disease or disorder, slowing or reversing its progression, or providing a cure to a disease or disorder, for example by removing its underlying cause.
- In the context of research, interventions seeking to modify the human genome for the acquisition of knowledge relevant to these permitted purposes may be carried out. Such knowledge may be relevant to the understanding of the biological factors associated with diseases or disorders or their mechanism of action, as well as the development of means to treat, diagnose or prevent the occurrence of such diseases or disorders.