



Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin *

Strasbourg, 24.I.2002

I. This Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin, 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 Working Party, by Dr Peter DOYLE (United Kingdom), member of the Working Party.

II. The Committee of Ministers has authorised the publication of this Explanatory Report on 8 November 2001.

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

Introduction

1. This Additional Protocol to the Convention on Human Rights and Biomedicine on the Transplantation of Organs and Tissues of Human Origin amplifies the principles embodied in the Convention, with a view to ensuring protection of people in the specific field of transplantation of organs and tissues of human origin.

2. The purpose of the Protocol is to define and safeguard the rights of organ and tissue donors, whether living or deceased, and those of persons receiving implants of organs and tissues of human origin.

Drafting of the Protocol

3. In 1991 in its Recommendation 1160, the Council of Europe Parliamentary Assembly recommended that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects". The same year, the Committee of Ministers instructed the CAHBI (*ad hoc* Committee of Experts on Bioethics), re-designated the CDBI (Steering Committee on Bioethics) "to prepare, ... 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".

(*) 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.

4. At its 14th meeting (Strasbourg, 5-8 November 1991), the CAHBI appointed the Working Party on Organ Transplantation, responsible for preparing the draft Protocol ⁽¹⁾. The CAHBI-CO-GT1, later the CDBI-CO-GT1, chaired by Mr Peter THOMPSON (United Kingdom), held its first meeting in January 1992 and began its activities concurrently with the CDBI's work on the Convention.

5. At the second meeting of the CDBI in April 1993 the Working Party submitted a draft Protocol on Organ Transplantation and in June 1994, the Ministers' Representatives agreed to declassify this document. However, as CDBI focused its efforts on the preparation of the Convention, the work on the draft Protocol was postponed until January 1997.

6. The Convention on Human Rights and Biomedicine was adopted by the Committee of Ministers on 19 November 1996 and was opened for signature on the 4 April 1997 in Oviedo (Spain). The CDBI, at its 11th meeting in June 1996, decided to give the CDBI-CO-GT1 ⁽²⁾, chaired by Dr Örn BJARNASON (Iceland), extended terms of reference to examine the draft Protocol on transplantation in the light of the Convention provisions.

7. This Protocol extends the provisions of the Convention on Human Rights and Biomedicine in the field of transplantation of organs, tissues and cells of human origin. The provisions of the Convention are to be applied to the Protocol. For ease of consultation by its users, the Protocol has been drafted in such a way that they need not keep referring to the Convention in order to understand the scope of the Protocol's provisions. However, the Convention contains principles which the Protocol is intended to develop. Accordingly, systematic examination of both texts may prove helpful and sometimes indispensable.

8. The draft Protocol, which was examined by the CDBI at its 15th meeting (7-10 December 1998), was declassified by the Committee of Ministers at its 658th meeting (2-3 February 1999, item 10.1) for the purposes of consultation. Those consulted, including member States, relevant European non-governmental organisations and particularly the Parliamentary Assembly (specifically the Social, Health and Family Affairs Committee, the Committee on Science and Technology and the Committee on Legal Affairs and Human Rights) have contributed to the development of the text. After re-examination, the CDBI finalised the text of the Protocol during its meeting from 5 to 8 June 2000.

9. The Protocol was approved by the CDBI on 8 June 2000 under the chairmanship of Dr Elaine GADD (United Kingdom). The Parliamentary Assembly gave an opinion on the Protocol, Opinion N° 227 (2001) of 25 April 2001, Professor Jean-François MATTEI being the Rapporteur. The Protocol was adopted by the Committee of Ministers on 8 November 2001.

10. The Protocol is accompanied by this explanatory report, 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 Working Party, by its member Dr Peter DOYLE (United Kingdom). It takes into account the discussions held in the CDBI and its Working Party entrusted with the drafting of the Protocol; it also takes into account the remarks and proposals made by Delegations. The Committee of Ministers has authorised its publication on 8 November 2001. The explanatory report is not an authoritative interpretation of the Protocol. Nevertheless it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the Protocol and make the scope of its provisions more comprehensible.

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Comments on the provisions of the Protocol

Title

11. The title identifies this instrument as the "Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, concerning Transplantation of Organs and Tissues of Human Origin".

12. The expression "of human origin" underlines the exclusion of xenotransplantation from the scope of the Protocol.

Preamble

13. The Preamble highlights the fact that Article 1 of the Convention on Human Rights and Biomedicine protecting the dignity and the identity of all human beings and guaranteeing everyone respect for their integrity, forms a suitable basis on which to formulate additional standards for safeguarding the rights and freedoms of donors, potential donors and recipients of organs and tissues.

14. In November 1987 the Third Conference of European Health Ministers convened in Paris dealt with organ transplantation, and a number of guidelines on the subject were adopted as a result. This Preamble echoes the main introductory paragraphs of their Final Declaration: while the transplantation of organs and tissues is an established part of the health services offered to the population, helping to save lives or improve their quality, emphasis is placed on the need to take specific measures to promote organ and tissue donation but also to prevent misuse of transplantation and the risk of commercialisation.

15. In addition, the Preamble stresses that it is important to take into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe on transplantation of organs and tissues, in particular Committee of Ministers Resolution (78) 29 on harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances and on the management of organ transplant waiting lists and waiting times, Recommendation No. REC (2001)5.

Chapter I – Object and scope

Article 1 – Object

16. This article specifies that the object of the Protocol is to protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

17. The term "everyone" is used in Article 1 because it is seen as the most concordant with the exclusion of embryonic and foetal organs or tissues from the scope of the Protocol as stated in Article 2 (see paragraph 24 below). The Protocol solely concerns removal of organs and tissues from someone who has been born, whether now living or dead, and the implantation of organs and tissues of human origin into someone else who has likewise been born.

Article 2 – Scope and definitions

18. This article sets out the scope of the Protocol and defines the main terms used.

Scope

19. The Protocol applies solely to the transplantation of organs, tissues and cells of human origin (see paragraph 22 below). Organs, tissues and cells used for implantation are normally obtained from any one of the following three sets of circumstances:

a. a living person may, under certain conditions, consent to the removal of an organ or tissue for the purpose of implantation into another person; Chapter III was therefore drafted with the aim of protecting living donors from the psychological and physical risks and the consequences of implantation, particularly with regard to confidentiality and burdens arising from the requirements of traceability;

b. organs or tissues may be removed from a deceased person and implanted into another person; Chapter IV was designed to regulate the various stages of removal from deceased persons and to guarantee in particular that no removal is carried out if the deceased person had objected to it;

c. a person who is undergoing a procedure for his/her own medical benefit may consent to any removed organ or tissue being implanted into another person; Chapter V was designed to specify the conditions under which such organs or tissues may be implanted, in particular by stipulating that specific information must be provided and informed consent or appropriate authorisation obtained.

20. The second paragraph of Article 2 states that the provisions of this Protocol applicable to tissues shall also apply to cells. Indeed Chapter VI of the Convention enunciates the fundamental principles with regard to removal of organs and tissues from living donors for the purpose of transplantation, but none of these provisions mention the term "cells". However, in many respects, transplantation of cells poses problems, particularly the consequences of testing and traceability, which are the same as those relating to the transplantation of tissues. Therefore, subject to Article 15, the Protocol applies the same regulations to the transplantation of cells as it does to the transplantation of tissues. In particular, the provisions concerning informed consent or authorisation by or on behalf of the donor, confidentiality, health and safety, and the prohibition of profit apply as for tissues.

21. The transplantation of haematopoietic stem cells, whatever their origin, comes within the scope of the Protocol, as does the transplantation of any kind of cells other than those that have been specifically excluded (see paragraphs 23 to 25 below). It should be emphasised that Recommendation No. R (98) 2 of the Committee of Ministers to member States on provision of haematopoietic progenitor cells is also relevant.

22. This Protocol does not apply to organs or tissues, whether genetically modified or not, removed from animals. These types of treatment are largely theoretical or at best experimental in the present state of scientific knowledge, and raise particular ethical problems. One should note that it is moreover foreseen that the issue of xenotransplantation will be addressed in another instrument presently under preparation. Thus it was agreed to place xenotransplantation outside the Protocol's scope.

23. Reproductive organs and tissues (comprising ova, sperm and their precursors) are excluded from the scope of the Protocol because organ and tissue transplantation is deemed to have different implications from those of medically assisted procreation and therefore should not be governed by the same rules. Therefore ovaries and testes are excluded but the uterus is not.

24. Transplantation of embryonic and foetal organs and tissue, including embryonic stem cells are also excluded from the scope of this Protocol. It is foreseen that these subjects will be addressed in another Protocol now being prepared on protection of the human embryo and foetus.

25. Blood and its derivatives covers blood and the products derived from blood for use in transfusion medicine. Blood and such products are thus subject to specific regulations, or specific standards, such as Recommendation R(95) 15 on the Preparation, use and quality assurance of blood components. Blood and its derivatives are therefore excluded from the scope of the Protocol. However, haematopoietic stem cells, whatever their origin, are within the scope of this Protocol as noted in paragraphs 21 and 109.

26. Implantation, in its traditional sense, does not include utilisation of tissues of human origin in the form of medical devices or pharmaceuticals; nevertheless, it was agreed that professional standards imply that the principles contained in this Protocol regarding namely safety, traceability, information and consent for such uses should be applicable *mutatis mutandis*.

Definitions

27. It is not a simple matter to decide what terms to use to signify the grafting or implantation of organs and tissues. In normal usage organs are "grafted" and tissues "implanted", or we refer to the "implantation of a graft". For the purposes of this Protocol it was agreed that in English "implantation" best described the surgical procedures involved.

28. There is also difficulty in agreeing on a scientifically precise definition of "organ" and "tissue". Traditionally an "organ" has been described as part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. In 1994 the Committee of Ministers adopted a definition of tissues as being "All constituent parts of the human body, including surgical residues, but excluding organs, blood, blood products as well as reproductive tissue such as sperm, eggs and embryos. Hair, nails, placentas and body waste products also excluded" (Recommendation No. R (94) 1 of the Committee of Ministers to member States on human tissue banks). These were useful definitions in the early days of transplantation when only a few solid organs were transplanted e.g. kidney, heart and liver. However, developments in transplantation have given rise to difficulties of definition. For example, only a part of an adult liver may be removed and transplanted into a child and the residual liver will re-grow and the transplant will grow to adult size. This is a liver transplant but is clearly not an "organ" transplant according to the traditional definitions. Conversely, if a whole bone is removed and transplanted, the body cannot replicate the bone, but bone is normally considered to be a tissue not an organ.

29. The Protocol sets out to overcome this difficulty by using the terms "organs" and "tissues" throughout the text, except in Article 10 (see paragraphs 30 to 32 below), so that all provisions apply to all parts of the body. The distinction between the removal of "tissues" and "cells" is also difficult. In effect, more than one cell may be considered to be a tissue. Similarly, the Protocol sets out to overcome this difficulty by stating that the provisions applicable to tissues shall also apply to cells. In the same way, unless specifically stated, explanations relating to tissues in this explanatory report also apply to cells.

30. It is nevertheless possible to distinguish between vascularised grafts that is organs or parts of organs which need re-connection of their blood supply, e.g. heart, lungs, liver, kidney, pancreas, bowel, from non vascularised tissue grafts and cells. The former, once removed from the body, normally only remain viable for relatively short periods and need to be transplanted within a few hours. Thus they cannot currently be processed and stored as can most tissues and cells. For this reason the rules relating to transplantation of vascularised "organs" may differ from those applying to tissues and cells.

31. Live organ donation is currently confined primarily to kidneys, lobes of either liver or lung, and isolated sections of small bowel. Their removal is a major procedure which carries a high risk. On the other hand, removal of tissues from a living donor generally carries a low risk of harm, and removal of cells might in certain cases involve an even smaller risk (see paragraph 90 below). These differences justify different rules; for this reason Article 10 deals

with the specific case of organ removal from a living person and Article 15 with the case of cell removal from a living person.

32. For the purposes of this Protocol, the term "organ" is accordingly applied to vascularised organs or parts of organs which require a major surgical procedure for removal and which need to be transplanted rapidly. The terms "tissues" and "cells" cover all other parts of the body except those specifically excluded.

33. Transplantation is defined as the whole process starting with removal of an organ or tissue from one person and ending with implantation of that organ or tissue into a different person. The person from whom the material is removed is generally designated by the word donor and the person into whom the material is implanted by the word recipient. Furthermore tissues such as bone may be processed and the resulting products implanted into more than one recipient. Similarly, cells may be cultured to supply more than one recipient. Increasingly livers removed from a deceased person are split so that even in the case of organ transplantation there may be more than one recipient. The safeguards in the Protocol apply to all possible steps in the transplant process and to all possible recipients. Moreover, they apply to the entire process of each step in transplantation; for example the word "removal" refers to all the medical interventions necessary for the removal, including investigation and preparation of the donor.

34. The provisions of this Protocol concerning removal apply if its purpose is transplantation. Removal of tissue carried out for any other purpose is not covered by the Protocol. Nevertheless, as stated in Article 20, when in the course of an intervention an organ or tissue is removed for a purpose other than donation for implantation, it may be suitable for implantation but may only be so used if the consequences and possible risks have been explained to that person and informed consent or, in the case of a person who is not able to consent, appropriate authorisation, has been obtained (see paragraphs 108 to 111 below). Besides, the protection afforded to recipients by this Protocol applies to all transplanted human material irrespective of why it was removed.

Chapter II – General provisions

Article 3 – Transplantation system

35. Parties to the Protocol undertake to ensure that a transplant system exists in their State within which transplant services operate. The nature or organisation of the system is not defined in this Protocol; it rests with individual States to decide whether to use local, regional, national or international organisations to meet the requirements of this article. As indicated in the 9th paragraph of the Preamble, institutions must be instrumental in ensuring that conditions protecting the rights and freedoms of donors, potential donors and recipients are observed.

36. The requirements of this article are that access to a transplant service is equitable – that is, all people, whatever their condition or background, must be equally able to be assessed by whatever transplant services are available. The concern is to ensure that there is no unjustified discrimination against any person within the jurisdiction of the Party who might benefit from a transplant. It has to be emphasised that there is a severe shortage of most organs and some of the tissues which can be transplanted. Scarce organs and tissues should be allocated so as to maximise the benefit of transplantation. The State-recognised system will be responsible for ensuring equitable access to assessment for transplantation and to transplant waiting lists.

37. The criteria by which organs and tissues are allocated should be determined in advance but be capable of amendment, be evaluated regularly and modified if or when circumstances change. The system governing transplantation may lay down different criteria according to the type of graft because of the particular characteristics and availability of the different organs and tissues.

Organs and tissues should be allocated according to medical criteria. This notion should be understood in its broadest sense, in the light of the relevant professional standards and obligations, extending to any circumstance capable of influencing the state of the patient's health, the quality of the transplanted material or the outcome of the transplant. Examples would be the compatibility of the organ or tissue with the recipient, medical urgency, the transportation time for the organ, the time spent on the waiting list, particular difficulty in finding an appropriate organ for certain patients (e.g. patients with a high degree of immunisation or rare tissue characteristics) and the expected transplantation result.

It should be noted that the transplantation of organs removed from a living donor takes place generally between persons having a close personal relationship; for this reason, the general provision in Article 3 is subject to the specific provisions contained in Chapter III, Articles 10 (Potential organ donors) and 14, paragraph 2, subparagraph ii (Protection of persons not able to consent to organ or tissue removal).

Organs removed from deceased persons should only be allocated to patients registered on an official waiting list. As to the tissues, there may be or there may not be an official waiting list.

Patients may be registered only on one official transplant list, be it regional, national or international so as not to prejudice the chances of others. However this principle does not preclude a system where a patient is registered on a local waiting which is part of a national waiting list (see Recommendation Rec (2001) 5 of the Committee of Ministers to Member States on the management of organ transplant waiting lists and waiting times).

The most important factor is to maximise equality of opportunity for patients and to do so by taking into account objective medical criteria. The allocation system should be as far as possible patient-oriented.

In case of international organ exchange arrangement, the procedures for distribution across participating countries should take into account the principle of solidarity within each country.

38. In order to ensure the allocation rules are transparent and well founded, they should state clearly who, within the system recognised by the member State, has the responsibility for the determination and the application of these rules. The person(s) or body(ies) responsible for organ and tissue allocation should be accountable for their decisions. Parties should bear in mind the provisions of Recommendation Rec (2001)5 on the management of organ transplant waiting lists and waiting times.

39. Traceability means being able to track all organs or tissues from donor to recipient and vice versa. It is required because it is impossible to eliminate entirely the risks of transmission of disease from donor to recipient and contamination of preserved material. Furthermore, new diseases or disease risks may emerge. Therefore for both public health reasons and the need to inform donors or recipients of potential problems that come to light following transplantation, it is important that any transplant material can be traced forward to recipients and back to the donor. For example, bone may be processed and turned into a variety of products with a long storage life available to treat multiple recipients. If a transmissible disease had been detected not at the outset but later in a recipient, donors would have to be traced to identify the one who transmitted the disease and unused products withdrawn. When seeking consent, both donors and recipients should be warned of such long-term consequences of transplantation and the possible need for prolonged surveillance. In addition, it may be necessary to analyse how organs and tissues were used to detect illegal or unethical use of such material, prevent organ and tissue trafficking and to validate allocation systems. For these reasons the transplant system must ensure a comprehensive system to enable all transplant material to be traced, without prejudice to the provisions on confidentiality set out in Article 23 (see paragraphs 122 and 123).

40. The question of methods for verifying the effectiveness with which the Parties implement systems for applying the various principles set out in article 3 is related to the general issue of Parties' honouring of the obligations in the Convention on Human Rights and Biomedicine, or any of its Protocols. In this context, reference should be made to i) the second paragraph of Article 1 of the Convention, which stipulates that "Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention", ii) Article 28 of this Protocol, according to which Articles 1 to 27 are regarded as additional articles to the Convention, and iii) Article 30 of the Convention, which empowers the Secretary General to request any Party to "furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention".

Article 4 – Professional standards

41. The provisions here use the wording of Article 4 of the Convention and apply to all health care professionals whether involved in the decision-making process or in performing a transplant. The text of the explanatory report of the Convention also applies in general, but some further explanation is required for the purposes of this Protocol.

42. The term "intervention" must be understood here in a broad sense. It covers all medical acts performed in connection with transplantation of organs or tissue for purposes of treating a patient. An intervention carried out in connection with experimental transplantation must furthermore comply with the rules governing research.

43. The relevant professional obligations and standards in accordance with which all interventions must be performed, are those laws, specific or general and any codes of practice or rules of conduct in force in the member State. Such codes or rules may take various forms such as health legislation, a code of professional practice or accepted medical ethical principles. Specifically, transplants should only be performed in accordance with the agreed allocation criteria. The rules and criteria may differ somewhat between countries but the fundamental principles of medical practice apply in all countries.

44. The competence of a doctor or other health care worker to take part in a transplant procedure must be determined in relation to the scientific knowledge and clinical experience appropriate to transplantation of organs or tissue at a given time. However, it is accepted that medical knowledge is rarely absolute and while acting according to the highest professional standards more than one therapeutic option may be perfectly justified. Recognised medical practice may therefore allow several alternative forms of intervention leaving some justified clinical freedom in the choice of methods or techniques. However, the choice of technique may affect the risk of inducing disease in the recipient, e.g. lymphoma or graft versus host disease, and such considerations should also be taken into account and the safest transplantation technique used.

45. Professional standards also require that organ and tissue implantation is only performed in accordance with a clear and specific medical indication for the recipient and not for any other reason such as a perceived social benefit. The recipient must have a defined medical problem which should be improved by a successful transplant before a transplant can be performed. The potential benefit of the procedure to the recipient must outweigh any risk. At all times, a decision to transplant must be taken only in the best interests of the patient.

46. Professional standards related to live transplantation require that, even if there is only one transplant team, different clinicians take responsibility for the care of the donor and the recipient, to ensure that the clinical needs of each party are properly and independently managed. In addition, it may be advisable to offer donors systematic long-term follow-up.

Article 5 – Information for the recipient

47. This article sets forth the recipient's right to be properly informed prior to implantation. Even though a transplant is intended to improve the health or even save the life of the recipient, the fact remains that the recipient shall be informed beforehand of the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention. This information must be as exact as possible and couched in terms which the recipient can understand. Information should be provided in a format appropriate to the needs of the recipient. In addition to proper discussion, written information which the recipient can study when there is adequate time may be particularly helpful. When the recipient is too ill to be able to give informed consent, in particular in emergency cases, the information shall also be given to the person or body providing the authorisation to the implantation, as foreseen by Article 6 of the Convention of Human Rights and Biomedicine.

Article 6 – Health and safety

48. This article deals with the health and safety aspects of the transplant process. It places an obligation on all those involved in the transplant process of organ and tissue to do everything that can be reasonably expected of them to ensure that organs and tissues are healthy and undamaged, that they are handled, transported and where appropriate preserved and stored by means that maximise their viability and minimise the risk of contamination. These measures will ensure that when grafted into a recipient, the risk to the health of the recipient has been minimised. However, it recognises that the risk of transmission of disease cannot be entirely eliminated. Exceptionally, circumstances may arise when some risk of transmission of disease to the recipient, or of failure of the organ or tissue graft, is acceptable if the consequence of not grafting is more serious, in particular, if the alternative is certain death. An assessment of the risks and benefits should be made on a case-by-case basis.

49. The expression "transmission of any disease" covers also the transmission of a pathology to the recipient which may or may not later develop into the disease (for instance, in the case of hepatitis C virus, the recipient might be infected but never develop overt disease).

50. The ultimate responsibility for deciding whether to use a particular graft lies with the recipient's implant team. However, it is essential that, in deciding whether to proceed with a graft, the practitioner has access to all the relevant information pertaining to the likely viability of the graft and the risk of transmission of disease. It is the responsibility of everyone involved to ensure that accurate information about the donor and the graft are collected, recorded and accompany the graft. The practitioners responsible for the removal of an organ or tissue have a duty to ensure that the donor is properly screened for transmissible diseases, both infectious and malignant. They are responsible for ensuring that a proper medical history has been obtained and that appropriate tests have either been performed or the necessary samples collected for testing.

51. However, organ transplantation sometimes has to be carried out in difficult circumstances as a matter of extreme urgency without having all the necessary information or knowing whether there is a risk for the recipient. In such circumstances, the doctor in charge should balance the risks and benefits and consequently, the implant should only be performed if the benefits to the recipient outweigh the risks and consent or authorisation has been given after information appropriate to the circumstances has been provided.

52. Moreover, because of the shortage of organs and some tissues, even when a disease risk is detected, it may not be appropriate to reject the donor without first checking whether there is a suitable recipient. The more urgent the type of transplant, the more essential it is to assess the risk and check whether there is any recipient who could benefit. For example in fulminant liver failure, the patient may only have a few hours to live and even a high risk organ may be considered preferable to almost certain death. In the case of tissue transplants which, except for bone marrow, are rarely if ever life saving, donor screening and testing should be more rigorous and disease transmission as far as possible prevented. Consequently, it may

still be reasonable to bank tissues, i.e. keep them in quarantine, awaiting the outcome of further investigations such as a post mortem or retesting of a living donor.

53. It is the responsibility of the persons involved in the removal of organs and tissues to use the highest standards of removal, preservation and, where appropriate, storage. They shall also take reasonable steps to ensure the continued quality and safety of the organs and tissues to minimise the risk of damage to the graft and to maximise its viability. In the case of organs this also means ensuring transport is available to minimise delays.

54. Those involved in the transport, preservation and storage of grafts are also responsible for ensuring that all relevant information has been obtained, checked, and accompanies the graft to the recipient, albeit nothing in this provision overrides the obligation of confidentiality as stated in Article 23.

55. Parties should also take account of other relevant national or international instruments in the field of health and safety, for example, guidance on the avoidance of transmission of infectious or malignant diseases during transplantation produced under the auspices of the European Health Committee ⁽¹⁾.

Article 7 – Medical follow-up See the Addendum

56. Article 7 of the Protocol states that a medical follow-up must be offered to living donors and recipients after transplantation. This is also a further specification of a principle of professional standards. The nature and duration of such follow-up should depend on the nature of the intervention and its potential impact on the individual's health. Short term follow up is essential to ensure recovery from the procedure. Life long follow up is essential for recipients requiring immunosuppressive therapy. Such follow-up is also desirable for living organ donors to enable any long term effects of the donation to be identified. However, living donors and even recipients cannot be forced to accept long term follow up.

Article 8 – Information for health professionals and the public

57. It is for Parties to the Protocol to ensure that appropriate information about organ and tissue transplantation is made available to health professionals and to the general public. The information should cover all the relevant medical, legal, social, ethical and other issues concerned, particularly sensitive issues such as the means of certifying death. In view of the organ shortage it is seen as advisable to inform all health care workers about the success and benefits of transplantation because of their ability to inform the general public. Parties should also use every opportunity to inform the general public directly of those same benefits and successes. Informing the general public is important in promoting organ and tissue donation but it is also important that people make up their minds on the issues in full knowledge of the facts. Information for the public should be available on donation both from the living and the deceased (however, the provision of this general information should be without prejudice to that which is given to living donors in accordance with Article 12). The information should include the consequences and risks of organs or tissues being implanted into another person. Testing may reveal unrecognised diseases which may have implications for any living donor and possibly for the relatives of deceased persons from whom organs and tissues are removed. The need to ensure traceability should also be explained as the consequences may not be realised until some time in the future. It is particularly important that such information is made available for people who may opt to become organ donors.

(1) A draft text on health and safety from the medical point of view is being prepared by the European Health Committee.

58. There is a very specific duty for the Parties, that is to ensure that the rules on consent and/or authorisation for organ or tissue retrieval and transplantation are well known and acceptable to the society. It is important to establish a relationship of trust between potential donors and the transplantation system. Transplant issues are constantly changing so the provision of information is an ongoing responsibility, not just an occasional one.

Chapter III – Organ and tissue removal from living persons

Article 9 – General rule See the Addendum

59. According to the first principle set out in the text, organs or tissues should be removed from deceased persons rather than from living donors whenever possible. Removing organs or tissues from living donors for implantation purposes always has consequences and may carry some risk for that donor. This implies that organs and tissues from living persons should not be used where an appropriate organ or tissue from a deceased person is available.

60. 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 and tissue removal, there is indeed no justification for resorting to this if there is another way of bringing the same benefit to the recipient, such as the use of artificial skin for instance. The transplant must therefore be necessary in the sense that there is no other treatment that would produce similar results. 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.

61. However, if the results of a living donor transplantation are expected to be significantly better than those expected utilising a graft removed from a deceased person, live donation may be the preferred therapeutic option for a particular recipient.

Article 10 – Potential organ donors

62. This article is specific to the removal of organs as defined in Article 2. It does not apply to the removal of tissues or cells. It defines the conditions under which, in addition of those of Article 9, living donation of an organ may be performed.

63. Those conditions would normally require that a close personal relationship, based on the principle of mutual aid, exists between the donor and recipient. The exact nature of the relationship is a matter for national law to determine and may depend on cultural or other local factors. Those with a close personal relationship with the recipient may include for instance members of the recipient's immediate family, parents, brothers, sisters, spouses or long-standing partners, godparents or close personal friends. Most countries have laws defining the nature of the relationship which is required to exist between donor and recipient and which makes live donation acceptable. The intention of such laws and this article is to prevent undue pressure to donate being brought to bear on people without a strong emotional relationship with the recipient.

64. However, not all national laws define close personal relationship, and where relationships are defined, the question of donation by a person not in such a relationship may be proposed. As there is some evidence that, despite the risks incurred, there may be perceptible long-term psychological benefit to organ donors who, even if not closely related, have helped improve the health or even save the life of a recipient, this article allows such circumstances to be taken into account. But they may only be considered when the national law sets out the conditions under which such circumstances may be considered. Those conditions include the provision of an appropriate independent body, for example an ethics committee, to consider each case. The body is responsible for ensuring that the other conditions required by law have been met, and that, for example, no coercion or inducement is involved. These provisions are thus an important safeguard against potential organ trafficking or the use of inducements.

65. The independent body required under this Article is not the same as the official body identified in Article 13 before which the living donor can give his/her consent. However, the law may provide for the independent body provided for by Article 10 to be the same as the competent body identified in Article 14, even if their responsibilities are different (see paragraph 87 below).

66. The reason for excluding tissues from this Article is that the therapeutic interests of a recipient who may not be known at the time of removal have to be taken into account. Here, the principles of Recommendation No. R (94) 1 of the Committee of Ministers to member States on human tissue banks are relevant.

Article 11 – Evaluation of risks for the donor

67. This article deals with evaluation of risk to the donor, which must be kept to a minimum. The health care professional's role here is twofold: to carry out whatever investigations may be required to evaluate the donor's state of health and therefore the potential risk of donation and, second, to take all reasonable measures to limit the risks to the donor without compromising the quality or viability of the organ or tissue removed for transplantation. The principal risks for the donor are the physical risks arising for the surgical procedure. However, there are also short and long-term psychological risks that also need to be fully assessed.

68. Whereas the word "investigation" covers all the examinations or tests to be performed, the word "intervention" is to be understood in a broad sense as covering all relevant medical acts.

69. The article places a ban on removal from a living donor where there is serious risk to the donor's life or health. This raises questions as to what a serious risk to the donor is and who judges the risk to be a serious one. Essentially there are three possible parties who may deem it a serious risk, the donor, the recipient or the medical team. For the purposes of this article, the decision about the risk is a matter for the transplant medical team looking after the donor or the body authorising the donation. The medical team should not propose a removal which they think presents an unacceptable risk even if the donor (for example, because he/she is a relative of the recipient) is ready to consent. In judging the risks involved, the donor's interests must take precedence, although in some circumstances the balance of risk to the donor compared to potential benefit to the recipient may be taken into consideration. The donation being acceptable or not depends not just on the physical risk associated with the procedure but must include psychological factors. Thus, the donor's emotional status should be independently assessed. An example of psychological harm is if the donor develops an undue sense of ownership towards the recipient or the recipient feels unduly obligated to the donor. If, following full assessment, the medical team looking after the donor judge there to be a significant risk of death or long term severe disability to the donor, the donation procedure should not go ahead.

Article 12 – Information for the donor

70. This article sets out the donor's right to be given appropriate information. In the case of donation of regenerative tissue, the most common instance is bone marrow transplantation between brothers and sisters, where the donor may be a minor. It is specifically to cater for this type of donation that the article requires the supply of information also to the representative, authority, person or body providing authorisation according to Article 14.2 of this Protocol.

71. There are two main requirements in the first part of the article. The information should be appropriate to explain the purpose and nature of the proposed removal as well as its consequences and risks, and the need for appropriate testing prior to the removal. It must be given prior to consent or authorisation and removal. Thus the information has to be as accurate as possible and given in terms the donor can understand, e.g. comparing the risks of a complication with other risks encountered in everyday life. In particular, in cases where the donor is a very young child, the content and form of the information presented must be

adapted to his or her age and capacity for understanding. The donor must be given adequate time to fully consider the information provided and discuss it with friends and/or relatives. In addition to proper discussion, written information which the donor can study when there is adequate time may be particularly helpful. If the donation requires an authorising party under Article 14.2 those discussions will normally include the potential donor.

72. The second paragraph defines a more specific right for the donor in that it requires all concerned to inform the potential donor of his/her rights and safeguards under domestic and international law. In particular, it states that the donor shall be informed of the right to have access to a source of independent advice about the risks of the removal procedure. This source of information, who may be a doctor or other suitably qualified health care worker, must be independent of the team or teams involved in the transplant. However, that person must have appropriate experience of the risks associated with donation and transplantation to be able to give proper advice. This advice can be requested by the donor if he/she wishes. An authorising party under Article 14.2 should have the same access to independent advice.

Article 13 – Consent of the living donor

73. This article is based on Article 5 of the Convention and requires that interventions in the field of organ and tissue transplantation can only be performed after a person has given free and informed consent which can be freely withdrawn at any time. In order to avoid undue pressure on the donor, he/she should be assured that he/she can refuse to donate or withdraw his/her consent at any time in complete confidence. To that end, the donor should be interviewed in private and helped to cope with the consequences of his/her decision.

74. In seeking the consent of the donor it is essential to discuss what should happen if for any reason the proposed recipient can not accept the donation. Any possible alternative use for the donated organ or tissue should be considered prior to the donation.

75. This article does not apply to persons who do not have capacity to consent to the removal of an organ, such persons being protected by the provisions of Article 14 and 15 of this Protocol.

76. The first paragraph of this article is more stringent than Article 5 of the Convention in that, for organ or tissue removal, the donor's consent must also be specific and given in written form or before an official body, a court, a judge or an official notary for example. The responsibility of this body is to ensure that consent is adequate and informed.

77. The second paragraph provides the freedom to withdraw consent to the removal at any time. There is no requirement for withdrawal of consent to be in writing or to follow any particular form. The donor need simply say no to the removal at any time, even if a procedure performed under local anaesthetic has commenced. Article 14 affords the same protection to donors of regenerative tissue lacking capacity to consent to their removal. However, professional standards and obligations may require that the team continue with the procedure if not to do so would seriously endanger the health of the donor.

78. This article concerning consent of the living donor is included in Chapter III "Organ and tissue removal from living persons". The consent, as well as withdrawal of consent, therefore only applies to the removal process. If, exceptionally, the donor seeks to withdraw consent to the agreed implantation after removal, national law or professional standards should provide a means of resolving such problems.

Article 14 – Protection of persons not able to consent to organ or tissue removal See the Addendum

79. Provisions relating to consent to organ or tissue removal for implantation apply in the case of live donors having the capacity to consent. Those relating to authorisation apply where a potential donor cannot formally give consent on account of incapacity.

80. Article 14 deals specifically with the question of the removal of organs or tissues from a living person not having the capacity to give consent. The principle is that this practice is prohibited. Article 14 follows the wording of Article 20 of the Convention.

81. Only in very exceptional circumstances may derogations be made to this rule and only for the removal of regenerative tissues. 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. Furthermore, Article 15 provides that Article 14, paragraph 2, indents ii. and iii. might not be applied, only in cases in which cell removal implies minimal risk and minimal burden for the donor.

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

83. Paragraph 2 therefore permits removal of bone marrow from a minor for the benefit of his or her brother or sister. The principle of mutual aid between very close members of a family and the possibility for psychological benefits to the donor arising from donation can justify, subject to certain conditions, 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 designed to protect the person who is incapable of giving consent, and these may be supplemented by national law. The conditions stated in the general rule of Article 9 also apply.

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

85. 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 kinship is distant and the chances for a successful transplant are not very likely because of tissue incompatibility.

86. Moreover, 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.

87. Furthermore, in keeping with Article 6 of the Convention, the authorisation of the representative of the person not able to consent or the authorisation of the authority or person or body provided for by law is needed before the removal can be carried out.

88. The agreement of the competent body 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. When the donor is an adopted person, it is for this body to verify that there has not been any misuse of the adoption process to enable a removal which would otherwise be forbidden. In this respect, it is important to note the important guarantees established in Article 14 for the protection of incapable persons and reinstated in the above paragraphs 80 to 86.

89. Finally, the removal may not be carried out if the potential donor objects in any way. This opposition, in whatever form, is decisive and must always be observed.

Article 15 – Cell removal from a living donor

90. Although transplantation procedures for cells generally pose problems similar to those related to the transplantation of tissues, there may however be a significant difference with regard to the risks arising from the removal of cells in comparison with removal of tissues. In certain cases such as obtaining a limited number of cells from the skin, the procedure itself may not involve more than minimal risk and minimal burden for the donor. In such cases, and only in such cases, it is foreseen that the Parties to the Protocol can choose not to apply the provisions of Article 14, paragraph 2, indents ii. and iii. The purpose of those provisions is to protect the donor from physical risks and from instrumentalisation contrary to their dignity, but where the risks and burdens are minimal it may not be appropriate to prohibit, for example, a minor donating cells to a family member other than a sibling.

91. One should also emphasise that the requirements of Article 14, paragraph 2, indents i., iv. and v. remain applicable. If compatibility is not medically required, it will always be possible to obtain a donor with capacity to consent. It is therefore not envisaged that cell removal be carried out on persons not able to consent outside of the immediate family circle.

92. This provision is an option for States, not an obligation; States can make use of this option at the time of ratification of the Protocol or at a later stage, depending on scientific and technical developments. Moreover, having in mind that technical developments in the future could permit the reconstitution of tissue in the laboratory from a limited number of cells, the inclusion of this option in the Protocol alleviates the potential need to amend it later if these foreseeable developments become reality.

93. Moreover, in recognition of the need to monitor the appropriate use of this provision, it was decided during the adoption of the draft Protocol by the CDBI that the States utilising this option would be requested to inform the other Parties by a notification addressed to the Secretary General.

Chapter IV – Organ and tissue removal from deceased persons

Article 16 – Certification of death

94. According to the first paragraph, a person's death must have been established before organs or tissues may be removed "in accordance with the law". It is the responsibility of the States to legally define the specific procedure for the declaration of death while the essential functions are still artificially maintained. In this respect, it can be noted that in most countries, the law defines the concept and the conditions of brain death.

95. The death is confirmed by doctors following an agreed procedure and only this form of death certification can permit the transplantation to go ahead. The retrieval team must satisfy themselves that the required procedure has been completed before any retrieval operation is started. In some States, this procedure for certification of death is separate from the formal issuance of the death certificate.

96. The second paragraph of Article 16 provides an important safeguard for the deceased person by ensuring the impartiality of the certification of death, by requiring that the medical team which certifies death should not be the same one that is involved in any stage of the transplant process. It is important that the interests of any such deceased person and the subsequent certification of death are, and are seen to be, the responsibility of a medical team entirely separate from those involved in transplantation. Failure to keep the two functions separate would jeopardise the public's trust in the transplantation system and might have an adverse effect on donation.

97. For the purposes of this Protocol, neonates including anencephalic neonates receive the same protection as any person and the rules on certification of death are applicable to them.

Article 17 – Consent and authorisation

98. Article 17 bars the removal of any organ or tissue unless the consent or authorisation required by national law has been obtained by the person proposing to remove the organ or tissue. This requires member States to have a legally recognised system specifying the conditions under which removal of organs or tissues is authorised. Furthermore, by virtue of Article 8, the Parties should take appropriate measures to inform the public, namely about matters relating to consent or authorisation with regard to removal from deceased persons (see paragraph 58 above).

99. If a person has made known their wishes for giving or denying consent during their lifetime, these wishes should be respected after his/her death. If there is an official facility for recording these wishes and a person has registered consent to donation, such consent should prevail: removal should go ahead if it is possible. By the same token, it may not proceed if the person is known to have objected. Nonetheless, consultation of an official register of last wishes is valid only in respect of the persons entered in it. Nor may it be considered the only way of ascertaining the deceased person's wishes unless their registration is compulsory.

100. The removal of organs or tissues can be carried out on a deceased person who has not had, during his/her life, the capacity to consent if all the authorisations required by law have been obtained. The authorisation may equally be required to carry out a removal on a deceased person who, during his/her life, was capable of giving consent but did not make known his wishes regarding an eventual removal post-mortem.

101. Without anticipating the system to be introduced, the Article accordingly provides that if the deceased person's wishes are at all in doubt, it must be possible to rely on national law for guidance as to the appropriate procedure. In some States the law permits that if there is no explicit or implicit objection to donation, removal can be carried out. In that case, the law provides means of expressing intention, such as drawing up a register of objections. In other countries, the law does not prejudge the wishes of those concerned and prescribes enquiries among relatives and friends to establish whether or not the deceased person was in favour of organ donation.

102. Whatever the system, if the wishes of the deceased are not sufficiently established, the team in charge of the removal of organs must beforehand endeavour to obtain testimony from relatives of the deceased. Unless national law otherwise provides, such authorisation should not depend on the preferences of the close relatives themselves for or against organ and tissue donation. Close relatives should be asked only about the deceased persons expressed or presumed wishes. It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved. Parties should make clear whether organ or tissue retrieval can take place if a deceased person's wishes are not known and cannot be ascertained from relatives or friends.

103. When a person dies in a country in which he/she is not normally resident, the retrieval team shall take all reasonable measures to ascertain the wishes of the deceased. In case of doubt, the retrieval team should respect the relevant applicable laws in the country in which the deceased is normally resident or, by default, the law of the country of which the deceased person is a national.

Article 18 – Respect for the human body

104. A dead body is not legally regarded as a person, but nonetheless should be treated with respect. This article accordingly provides that during removal the human body must be treated with respect and after removal the body should be restored as far as possible to its original appearance.

Article 19 – Promotion of donation

105. Because of the shortage of available organs, this article makes a provision for Parties to take all appropriate measures to promote the donation of organs and tissues.

106. The "appropriate" measures are not defined but will include the provisions on information to be provided to health professionals and to the public (Article 8), the need to set up a transplant system (Article 3) and to have recognised means of giving consent or authorisation (Article 17).

107. It is also appropriate to remember that organ and tissue removal from deceased persons has to be given priority if living donation is to be minimised, in conformity with Article 9. However, organ and tissue removal from deceased persons must itself carry safeguards and these are set out in Chapter IV.

Chapter V – Implantation of an organ or tissue removed for a purpose other than donation for implantation

Article 20 – Implantation of an organ or tissue removed for a purpose other than donation for implantation

108. In principle, this Protocol applies to the removal of organs or tissues for transplantation purposes. There are particular circumstances, however, in which those organs or tissues are removed for another purpose than donation for implantation but will nevertheless be donated at a later stage. The classic situation is the so-called "domino" transplant. When for instance a person needs a heart, or more often a lung transplant, it may be technically easier to remove their heart and lungs en bloc and replace them with a donor heart/lung block. Depending on the reason for the transplant, it is possible that the explanted heart, or at least the heart valves, will be in good condition and suitable for transplantation into another recipient. In this way the first recipient becomes a live donor for the second recipient. In the case of a "domino" heart transplant, the heart valves might be harvested from the second recipient's heart and be transplanted into a third person.

109. This article is also applicable where, in the course of a medical intervention, tissues are removed then processed and re-implanted into someone else, even if they are regarded as discarded tissues at the time of the intervention. In this respect, one could mention the following examples: the use of bone from femoral heads removed during hip replacement; the implant of a kidney removed for medical reasons; the use of vessels obtained from placentae or haematopoietic stem cells from cord blood.

110. The first paragraph of the article stresses the need to inform a person from whom organ or tissue have been removed for a purpose other than donation for implantation of the consequences associated with implantation of the organ or tissue into another person, namely the need for appropriate testing and recording of information which ensures the traceability of the organs or tissues; the information must include potential risks, for instance any modification, even minor, of the surgical procedure needed to retrieve the organ or tissue in the best possible condition for implantation. The first paragraph also stresses the need to obtain the informed consent of the person from whom organ or tissue have been removed or appropriate authorisation for the use of the organ or tissue for implantation. The first recipient of a heart can for instance be a child. In turn his/her heart or the valves which are removed

can be implanted in another child, if the persons providing authorisation have agreed after being duly informed.

111. As indicated in Article 2, the second paragraph of Article 20 provides that all the provisions of this Protocol, except for those in Chapters III and IV, which concern issues relating to removal for implantation purposes, apply to the situations referred to in paragraph 1. Indeed, the general provisions of the Protocol that guarantee fundamental rights (with regard namely to safety, confidentiality, non-commercialisation) will apply to the cases referred to in this article.

Chapter VI – Prohibition of financial gain

Article 21 – Prohibition of financial gain

112. This article applies the principle of human dignity as laid down in Article 1 of this Protocol.

113. It states in particular that the human body and its parts must not, as such, give rise to financial gain or comparable advantage. Under this provision, organs and tissues should not be bought or sold or give rise to direct financial gain for the person from whom they have been removed for a third party. Nor should the person from whom they have been removed, or a third party, gain any other advantage whatsoever comparable to a financial gain such as benefits in kind or promotion for example. A third party involved in the transplant process such as a health professional or a tissue bank may not make a profit from organs or tissues or any products developed from them (but see paragraph 115 below).

114. However, Article 21 states that certain payments that a donor may receive are not to be treated as financial gain within the meaning of this article. Essentially, apart from the last indent, these provide examples of expenses that may be incurred during or as a result of donation or other parts of the transplant process. This paragraph does not make exceptions to the principle laid down but gives examples of compensation to avoid possible financial disadvantage which may otherwise occur. In the case of the donor it allows for compensation for loss of earnings and other justifiable expenses.

115. The second indent of the first paragraph refers to payment of a justifiable fee for medical or technical services performed as part of the transplant process. Such acts might include the cost of retrieval, transport, preparation, preservation and storage of organs or tissues, which may legitimately give rise to reasonable remuneration.

116. The third indent allows donors to receive compensation for undue damage resulting from the removal. By undue damage is meant any harm whose occurrence is not a normal consequence of a transplant procedure. This provision refers to the compensation provided for in Article 25.

117. The second paragraph of this article makes it clear that any attempt to advertise anything to do with organ or tissue transplantation with a view to financial or equivalent gain for any party is prohibited.

118. This article refers solely to organs and tissues covered by the Protocol. The provision does not refer to such products as hair and nails for example, which are discarded tissues, and the sale of which is not an affront to human dignity.

Article 22 – Prohibition of organ and tissue trafficking

119. As stated by Article 21 of the Convention, the human body and its parts shall not, as such, give rise to financial gain. Any trade in organs and tissues for direct or indirect financial gain, as defined by Article 21 of this Protocol is prohibited. Organ trafficking and tissue trafficking are important examples of such illegal trading and of direct financial gain. Organ or tissue traffickers may also use coercion either in addition to or as an alternative to offering inducements. Such practices cause particular concern because they exploit vulnerable people and may undermine people's faith in the transplant system. This is why the prohibition of trafficking in organs and tissues is specifically referred to in Article 22.

120. This does not in any way reduce either the seriousness of infringements of other rights and principles enshrined in the Protocol, or the force of the prohibition of infringements of these rights and principles, as laid down in Articles 24 and 26.

121. In conformity with Article 26 of this Protocol, Parties shall provide for appropriate sanctions to deter organ and tissue trafficking or any attempt at commercial trade in organs or tissues.

Chapter VII – Confidentiality

Article 23 – Confidentiality

122. Article 23 lays down the principle of confidentiality. Preserving the anonymity of the person from whom organs or tissues have been removed may be impossible in certain circumstances, for example because of the requirement of an appropriate relation between the latter and the recipient in the case of living organ donation. However, personal data concerning persons from whom organs or tissues have been removed and recipients must nonetheless be treated as confidential and handled in accordance with the rules on professional confidentiality⁽¹⁾ and personal data protection. Here, the principles laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 (ETS 108) must be observed. In particular, Article 5.b of Convention 108 provides that personal data are "*stored for specified and legitimate purposes and not used in a way incompatible with those purposes*". Parties should take account of other national or international instruments, such as Recommendation (97) 5 of the Committee of Ministers to the member States on the protection of medical data and, where applicable, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on free movement of such data.

123. In transplantation, it is nevertheless essential that the principle of confidentiality should not prevent the medical team involved in any transplant process from obtaining the necessary information on the person from whom organs or tissues have been removed and the recipient, and keeping track of the exchange of organs or tissues between them, subject to appropriate safeguards to ensure adequate data protection. One such person may in fact supply several organs or tissues to be implanted in more than one recipient. If a disease is subsequently detected in that person, the recipients must be traceable. Equally, if a recipient of a transplant develops a disease which may have been transmitted, the person from whom organs or tissues had been removed must be identified, again to trace any other recipients. The rules applicable to traceability of organs and tissues are as set out in Article 3 paragraph 3 of this Protocol.

(1) A draft text on health and safety from the medical point of view is being prepared by the European Health Committee.

Chapter VIII – Infringements of the provisions of the Protocol

Article 24 – Infringements of rights or principles

124. 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 Protocol. It therefore covers not only infringements which have already begun and are ongoing but also the threat of an infringement.

125. The requisite judicial protection 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.

126. Under the Protocol, the appropriate protective machinery must be capable of operating rapidly as it must ensure that an infringement is 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.

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

Article 25 – Compensation for undue damage

128. This article sets forth the principle that the person who has suffered undue damage resulting from a transplantation is entitled to fair compensation. Like the Convention, the Protocol uses the expression "undue damage" because there can be damage which is inherent in the transplantation itself.

129. 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 either an act or an omission during the transplantation procedure. In order to give entitlement to compensation, the damage must result from the transplantation. Potential donors might be wronged during investigations to determine their suitability, as might recipients. In view of the altruistic nature of live organ donation, particular attention should be paid to the rights of donors and potential donors to an adequate compensation for damage resulting from transplantation.

130. Compensation conditions and procedures are not prescribed in this Article. In many cases, the national law 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.

131. On the subject of fair compensation, reference can be made to Article 41 of the European Convention on Human Rights, which allows the Court to afford just satisfaction to the injured party.

132. Article 21 of this Protocol makes reference to the aforementioned compensation in such terms as to exclude it from any payments constituting a financial gain or a comparable advantage.

Article 26 – Sanctions

133. Since the aim of the sanctions provided for in Article 26 is to guarantee compliance with the provisions of the Protocol, 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, 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 – Co-operation between Parties

Article 27 – Co-operation between Parties

134. International co-operation in transplantation matters is important for two main reasons. The first is that information about the organisation and effectiveness of services, successful methods of e.g. informing and educating the public or procuring organs, success rates and new developments should all be freely exchanged to help all States achieve the most effective transplant services possible within the resources available.

135. Secondly, difficulties of tissue matching or the urgency of the clinical condition may require access to a large or very large population if the transplant is to be successful. For example, matching for unrelated bone marrow transplants requires a very large pool of donors. People with fulminant liver failure may need a suitable organ within a few hours if they are to survive. If an organ becomes available in a country which has no suitable patient on its waiting list, there must be arrangements in place to allow that organ to be offered rapidly to patients on other transplant waiting lists if the organ is not to be wasted. States Party to this Protocol are expected to set up transborder links so as to facilitate the exchange of information and the transportation of organs and tissues between States but without prejudice to public safety as specified in Article 6 and the need for confidentiality as specified in Article 23.

Chapter X – Relation between this Protocol and the Convention, and re-examination of the Protocol

Article 28 – Relation between this Protocol and the Convention

136. As a legal instrument, the Protocol supplements the Convention. Once in force, the Protocol is subsumed into the Convention vis-à-vis Parties having ratified the Protocol. The provisions of the Convention are therefore to be applied to the Protocol.

137. Thus, Article 36 of the Convention, which sets out the conditions under which a State may make a reservation in respect of any particular provision of the Convention, will also apply to the Protocol. Using this provision States may, under the conditions set out in Article 36 of the Convention, make a reservation in respect of any particular provision of this Protocol.

Article 29 – Re-examination of the Protocol

138. This article provides that the Protocol 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. Article 32 of the Convention identifies this Committee as the Steering Committee on Bioethics (CDBI), or any other Committee so designated by the Committee of Ministers. The provisions of the Protocol to be re-examined would especially concern aspects of transplantation where scientific developments would give rise to particular ethical or legal issues; for example, it is conceivable that the question of removing cells from a living person will need to be reconsidered after a few years.

Chapter XI – Final clauses

Article 30 – Signature and ratification

139. Only States which have signed or ratified the Convention may sign this Protocol. Ratification of the Protocol is subject to prior or simultaneous ratification of the Convention. Under the provisions of Article 31 of the Convention, a State which has signed or ratified the Convention is not obliged to sign the Protocol or, if applicable, to ratify it.

ADDENDUM

Conclusions of the re-examination process of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin

In accordance with Article 29 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, the Committee on Bioethics (DH-BIO) proceeded to the re-examination of the Protocol. During its meeting of 19-22 June 2012, the DH-BIO adopted the conclusions hereafter, which were transmitted for information to the Committee of Ministers in September 2012 (document CM/Inf(2012)33).

1. In accordance with Article 32.1 of the Convention on Human Rights and Biomedicine (Oviedo Convention), the DH-BIO ⁽¹⁾ proceeded to the re-examination of the Additional Protocol to the Oviedo Convention concerning Transplantation of Organs and Tissues of Human Origin provided in Article 29 of this Protocol.

2. Following the discussion held on the basis of the comments sent by the Delegations, the DH-BIO concluded that developments in the field concerned did not warrant amendments to the Protocol.

3. The DH-BIO entrusted the Secretariat with the task of preparing the synthesis of the discussion held within the Committee, in particular on Articles 7, 9 and 14 of the Protocol. The DH-BIO considered that this synthesis which appears in Appendix these conclusions and that it examined at its 1st plenary meeting (19-22 June 2012), could usefully complement the explanatory report of the Additional Protocol drawn up under the authority of the Secretary General of the Council of Europe.

Appendix – Synthesis of the DH-BIO discussion in the light of the acquainted experience in the implementation of the Additional Protocol to the Convention on Human Rights and biomedicine concerning transplantation of organs and tissues of human origin

In keeping with Article 29 of the Additional Protocol, the Steering Committee on Bioethics (CDBI), and later the Committee on Bioethics (DH-BIO), began re-examining the Protocol in June 2010. In particular, Articles 7, 9 and 14 were discussed in the light of the experience gained from implementing the principles of the protocol.

(1) By decision of the Committee of Ministers, starting on 1st January 2012, the DH-BIO carries out the tasks assigned to the Steering Committee on Bioethics (CDBI) by the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

Article 7

This article states that appropriate medical follow-up shall be offered to living donors and recipients after transplantation. As pointed out in paragraph 56 of the explanatory report, the nature and duration of such follow-up should depend on the nature of the intervention and its potential impact on the individual's health. It is noted that this impact is not necessarily confined to the physical health of the individual, but may also relate to his/her mental health. The proposed follow-up could, if necessary, include an offer of psychological support.

Article 9

Under the general rule laid down in Article 9, there are three conditions which shall be met before an organ may be removed from a living donor:

- therapeutic benefit of the recipient,
- no suitable organ or tissue available from a deceased person, and
- no alternative therapeutic method of comparable effectiveness.

The Committee agrees on the need for further clarification, especially regarding the requirement as to the availability of organs and the requirement that they be of suitable quality.

In this context, it is noted that the conditions laid down in Article 9 are in keeping with a basic principle of protection of the living donor, for whom the removal of an organ or part of an organ always has implications and may present a health risk, particularly in the long term, which needs to be taken into account. While recognising the value of altruistic donation, the affirmation of this principle is also essential in the fight against trafficking in organs.

At the same time, it is difficult to escape the fact that there is a significant disparity between the growing number of people awaiting transplantation and the number of available organs. In the implementation of Article 9, the Committee notes that the availability of organs is taken into account in several countries not on a purely individual level but in relation to the system as a whole.

With regard to the quality of the organs, it is further noted that there has been a change in the quality of organs removed from deceased persons. The increasing age and the health condition of the deceased persons from whom these organs are removed are affecting the quality of the organs and hence the quality of the expected results of any transplantation using such organs. In this context, as pointed out in paragraph 61 of the explanatory report, "live donation may be the preferred therapeutic option".

Therefore, transplantation of organs removed from deceased persons and transplantation of organs removed from living donors, provided the conditions for ensuring protection of living donors are met, are not to be opposed and rather fulfil a therapeutic need.

Article 14

Paragraph 1 states that no organ or tissue removal may be carried out on a person who does not have the capacity to consent. It is noted that the capacity to consent is understood, under Article 5 of the Convention, in relation to a given intervention and that it is defined by domestic law. The provision of Article 14, paragraph 1, therefore applies to the removal of an organ or tissue from any person, whether adult or minor, who, according to the law, does not have the capacity to consent.