395/ME

Staatsverträge

BUNDESMINISTERIUM
FÜR ARBEIT, GESUNDHEIT UND SOZIALES

Dr. Hajek

GZ: 20.737/22-VIII/D/5/99 Wien, 11. Juni 1999

Betreff: **Entwurf eines Zusatzprotokolls zur Bioethikkonvention über die Transplantation von Organen und Geweben menschlichen Ursprungs**

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Das Bundesministerium für Arbeit, Gesundheit und Soziales übermittelt in der Anlage einen Entwurf des Leitungskomitees des Europarates für Bioethik für ein Zusatzprotokoll zur Konvention zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin über die Transplantation von Organen und Geweben menschlichen Ursprungs samt erläuterndem Bericht und einer deutschen Arbeitsübersetzung zur Erarbeitung eines österreichischen Standpunktes.

Es wird ersucht, allfällige Stellungnahmen bis längstens **30. Juli 1999** zu übermitteln.

Hochachtungsvoll
Für die Bundesministerin
MICHTNER

Für die Richtigkeit
der Ausfertigung:

A R B E I T S Ü B E R S E T Z U N G

Europarat

LENKUNGSAUSSCHUSS FÜR BIOETHIK (CDBI)

Entwurf eines Protokolls zum Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin über die Transplantation von Organen und Geweben menschlichen Ursprungs

Die vorliegende Fassung des Entwurfs eines Protokolls zum Übereinkommen über Menschenrechte und Biomedizin über die Transplantation von Organen und Geweben menschlichen Ursprungs ist vom Lenkungsausschuß für Bioethik (CDBI) auf seiner 15. Sitzung (7. bis 10. Dezember 1998) geprüft worden. Das Ministerkomitee hat seine Veröffentlichung zum Zwecke der Konsultation auf seiner 658. Sitzung vom 2. bis 3. Februar 1999 genehmigt.

Entwurf eines Protokolls zum Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin über die Transplantation von Organen und Geweben menschlichen Ursprungs

Präambel

Die Mitgliedstaaten des Europarates, die anderen Staaten und die Europäische Gemeinschaft, die dieses Zusatzprotokoll zum Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin (künftig: Übereinkommen über Menschenrechte und Biomedizin) unterzeichnen,

in der Erwägung, daß es das Ziel des Europarats ist, eine engere Verbindung zwischen seinen Mitgliedern herbeizuführen, und daß eines der Mittel zur Erreichung dieses Zieles darin besteht, die Menschenrechte und Grundfreiheiten zu wahren und fortzuentwickeln;

in der Erwägung, daß die Fortschritte in der medizinischen Wissenschaft, insbesondere auf dem Gebiet der Organ- und Gewebetransplantation dazu beitragen, Leben zu retten und die Lebensqualität zu verbessern;

in der Erwägung, daß die Transplantation von Organen und Geweben ein etablierter und wichtiger Teil der Gesundheitsleistungen ist, die der Bevölkerung angeboten werden;

in der Erwägung, daß ein Mangel an Organen und Geweben besteht, so daß geeignete Schritte unternommen werden sollten, um die Zahl der Organ-und Gewebespenden zu erhöhen, insbesondere durch Aufklärung der Bevölkerung über die Bedeutung der Organ- und Gewebetransplantation und durch die Förderung der europäischen Zusammenarbeit auf diesem Gebiet;

in der Erwägung der ethischen, psychologischen und sozio-kulturellen Probleme, die mit der Transplantation von Organen und Geweben verbundenen sind;

in der Erwägung, daß das Ziel des Übereinkommens über Menschenrechte und Biomedizin, insbesondere sein Artikel 1, der Schutz der Würde, der Identität und der Integrität aller Menschen ist;

in der Erwägung, daß der Mißbrauch der Organ- und Gewebetransplantation zu Handlungen führen kann, die das menschliche Leben, das menschliche Wohlbefinden oder die Menschenwürde gefährden;

in der Erwägung, daß die Organ- und Gewebetransplantation unter Bedingungen erfolgen soll, welche die Grundrechte und Grundfreiheiten der Spender, potentiellen Spender und Empfänger von Organen und Geweben gewährleisten;

übereinstimmend darin, daß bei der Förderung der Transplantation von Organen und Geweben im Interesse der Patienten in Europa die Notwendigkeit besteht, die persönlichen Rechte und Freiheiten des einzelnen zu schützen und die Kommerzialisierung von Teilen des menschlichen Körpers im Zusammenhang mit der Beschaffung, dem Austausch und der Verteilung von Organen und Geweben zu verhindern;

unter Berücksichtigung der früheren Arbeiten des Ministerkomitees und der Parlamentarischen Versammlung des Europarats auf diesem Gebiet;

entschlossen, im Hinblick auf die Organ- und Gewebetransplantation die notwendigen Maßnahmen zu ergreifen, um den Schutz der Menschenwürde sowie der Grundrechte und Grundfreiheiten des Menschen zu gewährleisten;

sind wie folgt übereingekommen:

Kapitel I
(Gegenstand und Anwendungsbereich)

Artikel 1 (Gegenstand)

Die Vertragsparteien schützen die Würde und die Identität jeder Person und gewährleisten ohne Diskriminierung die Wahrung ihrer Integrität sowie ihrer sonstigen Grundrechte und Grundfreiheiten im Hinblick auf die Transplantation von Organen und Geweben menschlichen Ursprungs.

Artikel 2 (Anwendungsbereich und Begriffsbestimmungen)

1. Dieses Protokoll findet Anwendung auf die Transplantation von Organen und Geweben menschlichen Ursprungs zu therapeutischen Zwecken.

Dieses Protokoll ist nicht anwendbar:

a) auf Blut und Blutbestandteile,

b) auf Fortpflanzungsorgane und - gewebe;

c) auf embryonale oder fötale Organe und Gewebe.

2. Für die Zwecke dieses Protokolls

- umfaßt der Begriff „Transplantation" die Entnahme eines Organs oder Gewebes bei einer Person und die Implantation dieses Organs oder Gewebes bei einer anderen Person, einschließlich sämtlicher Konservierungs- oder Aufbewahrungsverfahren;

- bezieht sich der Begriff "Entnahme", falls nicht anders angegeben, auf die Entnahme zu Transplantationszwecken.

Kapitel II
(Allgemeine Bestimmungen)

Artikel 3 (Transplantationssystem)

Jede Vertragspartei gewährleistet, daß ein System vorhanden ist, das den Patienten gleichen Zugang zu den Transplantationsleistungen ermöglicht und das sicherstellt, daß Organe und Gewebe nach transparenten und gebührend begründeten Kriterien unter besonderer Berücksichtigung medizinischer Kriterien verteilt werden.

Die Personen oder Stellen, die für die Verteilung verantwortlich sind, werden in diesem Rahmen bestimmt.

Das Transplantationssystem stellt die Sammlung und Aufzeichnung der Informationen sicher, die erforderlich sind, um die Rückverfolgbarkeit von Organen und Geweben zu gewährleisten.

Artikel 4 (Berufspflichten und Verhaltensregeln)

Jede Intervention im Bereich der Transplantation von Organen und Geweben muß nach den einschlägigen Rechtsvorschriften, Berufspflichten und Verhaltensregeln erfolgen.

Artikel 5 (Aufklärung des Empfängers)

Der Empfänger und wenn erforderlich die Person oder die Stelle, welche die Einwilligung zur Implantation erteilen, sind zuvor angemesen über Zweck und Art der Implantation, ihre Folgen und Risiken sowie über Alternativen zu der Intervention aufzuklären.

Artikel 6 (Gesundheit und Sicherheit)

Die an der Transplantation von Organen und Geweben beteiligten Angehörigen der Gesundheitsberufe haben alle angemessenen Maßnahmen zu ergreifen, um die Risiken der Übertragung von Krankheiten auf den Empfänger so gering wie möglich zu halten und alle Handlung zu vermeiden, die die Eignung eines Organs oder Gewebes für die Implantation beeinträchtigen könnten.

Artikel 7 (Aufklärung der Angehörigen der Gesundheitsberufe und der Öffentlichkeit)

Die Vertragsparteien stellen den Angehörigen der Gesundheitsberufe und der breiten Öffentlichkeit Informationen über den Bedarf an Organen und Geweben zur Verfügung. Weiters informieren sie über die Bedingungen für die Entnahme und Implantation von Organen und Gewebe, einschließlich der Fragen der Einwilligung, insbesondere im Hinblick auf die Entnahme bei verstorbenen Personen.

Kapitel III
(Entnahme von Organen und Geweben von lebenden Personen)

Artikel 8 (Allgemeine Regel)

Einer lebenden Person darf ein Organ oder Gewebe nur zum therapeutischen Nutzen eines Empfängers und nur dann entnommen werden, wenn weder ein geeignetes Organ oder Gewebe einer verstorbenen Person verfügbar ist noch eine alternative therapeutische Methode von vergleichbarer Wirksamkeit besteht.

Artikel 9 (Potentielle Spender)

Die Entnahme von Organen von lebenden Spendern darf nur zum Nutzen eines Empfängers, zu dem der Spender eine von der Rechtsordnung festgelegte angemessene Beziehung hat, oder andernfalls nach Billigung durch eine geeignete unabhängige Stelle erfolgen.

Artikel 10 (Einschätzung der Risiken für den Spender)

Vor der Entnahme von Organen und Geweben sind angemessene medizinische Untersuchungen und Interventionen zur Einschätzung und Verringerung der physischen und psychischen Risiken für die Gesundheit des Spenders durchzuführen.

Die Entnahme darf nicht durchgeführt werden, wenn für das Leben oder die Gesundheit des Spenders ein ernsthaftes Risiko besteht.

Artikel 11 (Aufklärung des Spenders)

Der Spender und wenn erforderlich die Person oder die Stelle, die die Einwilligung gemäß Artikel 13 Absatz 2 dieses Protokolls erteilen, sind zuvor in angemessener Weise über Zweck und Art der Entnahme sowie deren Folgen und Risiken aufzuklären.

Sie sind auch über die Rechte und die Sicherheitsmaßnahmen aufzuklären, die von der Rechtsordnung zum Schutz des Spenders vorgesehen sind. Insbesondere sind sie über das Recht auf unabhängige medizinische Beratung über derartige Risiken durch einen Angehörigen der Gesundheitsberufe mit entsprechender Erfahrung aufzuklären, der weder an der Entnahme des Organs oder Gewebes noch an den nachfolgenden Transplantationsverfahren beteiligt ist.

Artikel 12 (Einwilligung des lebenden Spenders)

Vorbehaltlich des Artikels 13 dieses Protokolls darf ein Organ oder Gewebe von einem lebenden Spender nur entnommen werden, nachdem

die betroffene Person nach Aufklärung ihre freie und ausdrückliche Einwilligung eigens für diesen Fall entweder in schriftlicher Form oder vor einer amtlichen Stelle erteilt hat.

Die betroffene Person kann ihre Einwilligung jederzeit frei widerrufen.

Artikel 13 (Schutz einwilligungsunfähiger Personen bei Organ- und Gewebeentnahme)

1. Einer Person, die nicht fähig ist, die Einwilligung nach Artikel 12 dieses Protokolls zu erteilen, dürfen weder Organe noch Gewebe entnommen werden.

2. In Ausnahmefällen und nach Maßgabe der durch die Rechtsordnung vorgesehenen Schutzbestimmungen darf die Entnahme regenerierbaren Gewebes bei einer einwilligungsunfähigen Person zugelassen werden, wenn die folgenden Voraussetzungen erfüllt sind:

- Ein geeigneter einwilligungsfähiger Spender steht nicht zur Verfügung;

- der Empfänger ist ein Bruder oder eine Schwester des Spenders;

- die Spende muß geeignet sein, das Leben des Empfängers zu retten;

- die Einwilligung ihres gesetzlichen Vertreters oder einer von der Rechtsordnung dafür vorgesehenen Behörde, Person oder Stelle ist eigens für diesen Fall und schriftlich und mit der Billigung der zuständigen Stelle erteilt worden;

- der in Frage kommende Spender lehnt nicht ab.

Kapitel IV
(Entnahme von Organen und Geweben von verstorbenen Personen)

Artikel 14 (Förderung der Organspende)

Die Vertragsparteien ergreifen als Reaktion auf den Mangel an Organen und Geweben alle geeigneten Maßnahmen, um die Beschaffung von Organen und Geweben von verstorbenen Personen in Übereinstimmung mit den in diesem Protokoll aufgeführten Bestimmungen zu fördern.

Artikel 15 (Feststellung des Todes)

Organe oder Gewebe dürfen einer verstorbenen Person erst entnommen werden, wenn der Tod dieser Person ist in Übereinstimmung mit der Rechtsordnung festgestellt worden ist.

Die Ärzte, die für die Betreuung potentieller Organ- oder Gewebeempfänger verantwortlich sind, oder diejenigen, die an der Entnahme von Organen oder Geweben von Spendern oder an den nachfolgenden Transplantationsvorgängen unmittelbar beteiligt sind, dürfen nicht dieselben Ärzte sein, die den Tod des in Frage kommenden Spender feststellen.

Artikel 16 (Einwilligung)

Organe oder Gewebe dürfen dem Körper einer verstorbenen Person nur entnommen werden, wenn die nach der Rechtsordnung erforderliche Einwilligung erteilt worden ist.

Die Entnahme darf nicht erfolgen, wenn die verstorbene Person ihr widersprochen hat.

Artikel 17 (Achtung des menschlichen Körpers)

Bei der Transplantation ist der menschliche Körper mit Achtung zu behandeln und es sind alle angemessenen Maßnahmen zu ergreifen, um das Erscheinungsbild des Leichnams wiederherzustellen.

Kapitel V
(Verwendung eines entnommenen Organs oder Gewebes)

Artikel 18 (Verwendung eines entnommenen Organs oder Gewebes)

Wird bei einer Intervention ein Organ oder Gewebe zu anderen Zwecken als zur Spende für die Implantation entnommen, so darf es nur in Übereinstimmung mit angemessenen Informations- und Einwilligungsverfahren transplantiert werden.

Kapitel VI
(Verbot finanziellen Gewinns)

Artikel 19 (Verbot finanziellen Gewinns)

1. Der menschliche Körper und seine Teile dürfen als solche nicht zur Erzielung eines finanziellen Gewinns oder vergleichbarer Vorteile verwendet werden.

Die vorstehende Bestimmung verbietet solche Zahlungen nicht, die keinen finanziellen Gewinn oder vergleichbaren Vorteil darstellen, insbesondere:

- die Entschädigung lebender Spender für Verdienstausfall und für sonstige berechtigte Ausgaben, die durch die Entnahme oder die damit verbundenen Untersuchungen verursacht wurden;

- die Zahlung einer vertretbaren Vergütung für berechtigte medizinische oder damit verbundene technische Leistungen, die im Zusammenhang mit der Transplantation erbracht wurden;

- die Entschädigung im Falle eines ungerechtfertigten Schadens infolge der Entnahme von Organen und Gewebe von lebenden Personen.

2. Werbung hinsichtlich des Bedarfs an oder der Verfügbarkeit von Organen oder Geweben, in der Absicht, einen finanziellen Gewinn oder vergleichbaren Vorteil anzubieten oder zu erlangen, ist verboten.

Kapitel VII
(Vertraulichkeit)

Artikel 20 (Vertraulichkeit)

Die Identität und alle anderen personenbezogenen Daten des Spenders und des Empfängers sind als vertraulich anzusehen und nach den Regeln zum Schutz der Privatsphäre zu behandeln.

Die Auslegung dieser Bestimmung läßt die Bestimmungen unberührt, die den Zugang zu den erforderlichen Daten über Spender oder Empfänger von Organen und Geweben erlauben, soweit dies für medizinische Zwecke einschließlich der in Artikel 3 dieses Protokolls vorgesehenen Rückverfolgbarkeit erforderlich ist.

Kapitel VIII
(Verletzung von Bestimmungen des Protokolls)

Artikel 21 (Verletzung von Rechten oder Grundsätzen)

Die Vertragsparteien gewährleisten einen geeigneten Rechtsschutz, der darauf abzielt, eine widerrechtliche Verletzung der in diesem Protokoll verankerten Rechte und Grundsätze innerhalb kurzer Frist zu verhindern oder zu beenden.

Artikel 22 (Schadenersatz)

Jede Person, die durch ein Transplantationsverfahren in ungerechtfertigter Weise Schaden erlitten hat, hat Anspruch auf angemessenen Schadenersatz nach Maßgabe der durch die Rechtsordnung vorgesehenen Voraussetzungen und Modalitäten.

Artikel 23 (Sanktionen)

Die Vertragsparteien sehen angemessene Sanktionen für Verletzungen von Bestimmungen dieses Protokolls vor.

Kapitel IX
(Zusammenarbeit zwischen den Vertragsparteien)

Artikel 24 (Zusammenarbeit zwischen den Vertragsparteien)

Die Vertragsparteien ergreifen geeignete Maßnahmen, um eine wirksame Zusammenarbeit auf dem Gebiet der Transplantation von Organen, unter anderem durch Austausch von Informationen, sicherzustellen.

Sie ergreifen insbesondere geeignete Maßnahmen, um die rasche und sichere Beförderung von Organen in ihr Hoheitsgebiet oder aus ihrem Hoheitsgebiet zu ermöglichen.

Kapitel X
(Schlußbestimmungen)

Artikel 25 (Verhältnis zwischen dem Übereinkommen und diesem Protokoll)

Die Vertragsparteien sehen die Artikel 1 bis 24 dieses Protokolls als ergänzende Artikel zu dem Übereinkommen über Menschenrechte und Biomedizin an, und alle Bestimmungen des Übereinkommens über Menschenrechte und Biomedizin sind demgemäß anzuwenden.

Artikel 26 (Unterzeichnung und Ratifikation)

Dieses Protokoll liegt für die Unterzeichner des Übereinkommens zur Unterzeichnung auf. Es bedarf der Ratifikation, Annahme oder

Genehmigung. Ein Unterzeichner kann dieses Protokoll ohne vorherige oder gleichzeitige Ratifikation, Annahme oder Genehmigung des Übereinkommens nicht ratifizieren, annehmen oder genehmigen. Die Ratifikations-, Annahme- oder Genehmigungsurkunden werden beim Generalsekretär des Europarats hinterlegt.

Artikel 27 (Inkrafttreten)

1. Dieses Protokoll tritt am ersten Tag des Monats in Kraft, der auf einen Zeitabschnitt von drei Monaten nach dem Tag folgt, an dem 5 Staaten, darunter mindestens vier Mitgliedstaaten des Europarats, nach Artikel 26 ihre Zustimmung ausgedrückt haben, durch dieses Protokoll gebunden zu sein.

2. Für jeden Unterzeichner, der später seine Zustimmung ausdrückt, durch dieses Protokoll gebunden zu sein, tritt es am ersten Tag des Monats in Kraft, der auf einen Zeitabschnitt von drei Monaten nach Hinterlegung seiner Ratifikations-, Annahme- oder Genehmigungsurkunde folgt.

Artikel 28 (Beitritt)

1. Nach Inkrafttreten dieses Protokolls kann jeder Staat, der dem Übereinkommen beigetreten ist, auch diesem Protokoll beitreten.

2. Der Beitritt erfolgt durch Hinterlegung einer Beitrittsurkunde beim Generalsekretär des Europarats und wird am ersten Tag des Monats wirksam, der auf einen Zeitabschnitt von drei Monaten nach ihrer Hinterlegung folgt.

Artikel 29 (Kündigung)

1. Jede Vertragspartei kann dieses Protokoll jederzeit durch eine an den Generalsekretär des Europarats gerichtete Notifikation kündigen.

2. Die Kündigung wird am ersten Tag des Monats wirksam, der auf einen Zeitabschnitt von drei Monaten nach Eingang der Notifikation beim Generalsekretär folgt.

Artikel 30 (Notifikation)

Der Generalsekretär des Europarates notifiziert den Mitgliedstaaten des Europarates, der Europäischen Gemeinschaft, jedem Unterzeichner, jeder Vertragspartei und jedem anderen Staat, der zum Beitritt zu dem Übereinkommen eingeladen worden ist,

a) jede Unterzeichnung;
b) jede Hinterlegung einer Ratifikations-, Annahme-, Genehmigungs- oder Beitrittsurkunde;
c) jeden Zeitpunkt des Inkrafttretens dieses Protokolls nach Artikel 27 und 28;
d) jede andere Handlung, Notifikation oder Mitteilung im Zusammenhang mit diesem Protokoll.

Zu Urkund dessen haben die hierzu gehörig befugten Unterzeichneten dieses Protokoll unterschrieben.

Geschehen zu ... am .... in englischer und französischer Sprache, wobei jeder Wortlaut gleichermaßen verbindlich ist, in einer Urschrift, die im Archiv des Europarats hinterlegt wird. Der Generalsekretär des Europarats übermittelt allen Mitgliedstaaten des Europarats, den Nichtmitgliedstaaten, die an der Ausarbeitung dieses Protokolls beteiligt waren, und allen zum Beitritt zu dem Übereinkommen eingeladenen Staaten sowie der Europäischen Gemeinschaft beglaubigte Abschriften.

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Committee of Ministers
Comité des Ministres

Strasbourg, 6 January 1999

Restricted
CM(98)212 Addendum I

For consideration at the 658th meeting
of the Ministers' Deputies
(2-3 February 1999, A level, item 10.1)

STEERING COMMITTEE ON BIOETHICS (CDBI)

Abridged Report of the 15th meeting of the CDBI
(Strasbourg, 7-10 December 1998)

PART A
Draft Additional Protocol
to the Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine, on Transplantation of Organs and Tissues of Human Origin

PART B
Draft Explanatory Report

The current draft additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin (Part A of this Addendum) has been examined by the Steering Committee on Bioethics (CDBI) during its 15th meeting (7-10 December 1998). The Committee of Ministers has authorised its publication for consultation purposes at its 658th meeting (2-3 February 1999, Item 10.1).

The current draft Explanatory Report to the draft additional Protocol on Transplantation of Organs and Tissues of Human Origin (Part B of this Addendum) has been examined by the Steering Committee on Bioethics (CDBI) during its 15th meeting (7-10 December 1998). This text provides information to clarify the object and purpose of the Protocol and make the scope of its provisions more comprehensible. The Committee of Ministers has authorised its publication at its 658th meeting (2-3 February 1999, Item 10.1).

Internet : www.coe.fr/cmline **(password access)**
Intranet : home/cmline

PART A

DRAFT PROTOCOL ON TRANSPLANTATION OF ORGANS AND TISSUES OF HUMAN ORIGIN

Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this 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 (hereinafter referred to as "Convention on Human Rights and Biomedicine"),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that progress in medical science, in particular in the field of organ and tissue transplantation, contributes to saving lives and improving their quality;

Considering that transplantation of organs and tissues is an established and important part of the health services offered to the population;

Considering that there are shortages of organs and tissues, appropriate action should be taken to increase organ and tissue donation, in particular by informing the public of the importance of organ and tissue transplantation and by promoting in Europe co-operation in this field;

Considering the ethical, psychological and socio-cultural problems inherent in the transplantation of organs and tissues;

Considering that the aim of the Convention on Human Rights and Biomedicine, in particular Article 1, is to protect the dignity, the identity and the integrity of all persons;

Considering that the misuse of organ and tissue transplantation may lead to acts endangering human life, well-being or dignity;

Considering that organ and tissue transplantation should take place under conditions protecting the rights and freedoms of donors, potential donors and recipients of organs and tissues;

Agreeing that in facilitating the transplantation of organs and tissues in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ and tissue procurement, exchange and allocation activities;

Taking into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to organ and tissue transplantation;

Have agreed as follows:

Chapter I
(Object and scope)

Article 1 (Object)

The Parties shall 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.

Article 2 (Scope and definitions)

1. This Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.

The protocol does not apply:

a. to blood and blood derivatives,
b. to reproductive organs and tissue,
c. to embryonic or foetal organs and tissues.

2. For the purposes of this Protocol:

- the term "transplantation" covers the removal from one person of an organ or tissue and the implantation of that organ or tissue into another person, including any procedure of preservation or storage;

- unless otherwise indicated, the term "removal" refers to removal for the purposes of transplantation.

Chapter II
(General provisions)

Article 3 (Transplantation system)

Each Party shall guarantee that a system exists to provide equitable access to transplantation services for patients which ensures that organs and tissue are allocated in conformity with transparent and duly justified rules taking particular account of medical criteria.

The persons or bodies responsible for the allocation decision shall be designated within this framework.

The transplantation system shall ensure the collection and recording of the information required to ensure traceability of organs and tissues.

Article 4 (Professional standards and medical indications)

Any intervention in the field of organ or tissue transplantation must be carried out in accordance with relevant professional obligations and standards.

Article 5 (Information for the recipient)

The recipient and, where appropriate, the person or body providing authorisation to the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks as well as on the alternatives to the intervention.

Article 6 (Health and safety)

All professionals involved in organ or tissue transplantation shall take all reasonable measures to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ or tissue for implantation.

Article 7 (Information for health professionals and public)

The Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissue, including matters relating to consent or authorisation, in particular with regard to removal from deceased persons.

Chapter III
(Organ and tissue removal from living persons)

Article 8 (General rule)

Removal of organs or tissues from a living person may be carried out solely for the therapeutic benefit of a recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

Article 9 (Potential donors)

Organ removal from a living donor shall only be carried out for the benefit of a recipient with whom the donor has an appropriate relationship as defined by law, or otherwise with the approval of an appropriate independent body.

Article 10 (Evaluation of risks for the donor)

Before organ and tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor.

The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 11 (Information for the donor)

The donor and, where appropriate, the person or body providing authorisation according to Article 13.2 of this Protocol, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks.

They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 12 (Consent of the living donor)

Subject to Article 13 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body.

The person concerned may freely withdraw consent at any time.

Article 13 (Protection of persons not able to consent to organ and tissue removal)

1. No organ and tissue removal may be carried out on a person who does not have the capacity to consent under Article 12 of this Protocol.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

- there is no compatible donor available who has the capacity to consent;
- the recipient is a brother or sister of the donor;
- the donation has the potential to be life-saving for the recipient;
- the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body;
- the potential donor concerned does not object.

Chapter IV
(Organ and tissue Removal from deceased persons)

Article 14 (Promotion of donation)

The Parties shall respond to shortages of organs and tissues by taking all appropriate measures to promote the procurement of organs and tissue from deceased persons in accordance with the provisions laid down in this Protocol.

Article 15 (Certification of death)

Organs or tissue shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.

The doctors having responsibilities for the care of potential organ or tissue recipients, or who participate directly in removal of organs or tissues from a donor, as well as subsequent transplantation procedures, shall not be the same doctors certifying the death of the potential donor.

Article 16 (Consent and authorisation)

Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained.

The removal may not be carried out if the deceased person had objected to it.

Article 17 (Respect of the human body)

In transplantation the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.

Chapter V
(Disposal of a removed organ or tissue)

Article 18 (Disposal of a removed organ or tissue)

When in the course of an intervention an organ or tissue is removed for a purpose other than donation for implantation, it may be transplanted only if this is done in conformity with appropriate information and consent procedures.

Chapter VI
(Prohibition of financial gain)

Article 19 (Prohibition of financial gain)

1. The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related examinations;

- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

- compensation in case of undue damage resulting from the removal of organs and tissue from living persons.

2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Chapter VII
(Confidentiality)

Article 20 (Confidentiality)

The identity and any other personal data relating to either donor or recipient shall be considered as confidential and treated according to the rules relating to protection of private life.

This provision shall be interpreted without prejudice to the provisions making possible access to the necessary information about the donor(s) or the recipient(s) of organs and tissues insofar as this is required for medical purposes including traceability as provided for in Article 3 of this Protocol.

Chapter VIII
(Infringements of the provisions of the Protocol)

Article 21 (Infringements of rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to stop any unlawful infringement of the rights and principles set forth in this Protocol at short notice.

Article 22 (Compensation for undue damage)

Any person who has suffered undue damage resulting from transplantation procedures is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 23 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

Chapter IX
(Co-operation between Parties)

Article 24 (Co-operation between Parties)

The Parties shall take appropriate measures to ensure that there is efficient co-operation between them on organ transplantation, inter alia through information exchange.

In particular they shall undertake appropriate measures to facilitate the rapid and safe transportation of organs to and from their territory.

Chapter X
(Final provisions)

Article 25 (Relation between the Convention and this Protocol)

As between the Parties, the provisions of Articles 1 to 24 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of the Convention on Human Rights and Biomedicine shall apply accordingly.

Article 26 (Signature and ratification)

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 27 (Entry into force)

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 26.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 28 (Accession)

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 29 (Denunciation)

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 30 (Former Article 27) (Notification)

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:

a. any signature;
b. the deposit of any instrument of ratification, acceptance , approval or accession;
c. any date of entry into force of this Protocol in accordance with Articles 27 and 28;
d. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at ..., this ..., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

PART B

Draft Explanatory Report to the draft Additional Protocol to the Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine, on Transplantation of Organs and Tissues of Human Origin

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".

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.

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[1] Membership of the CAHBI-CO-GT1: Mr Örn BJARNASON (Iceland), Mr Radkin HONZÁK (Czechoslovakia), Ms Sophie JACQUOT-DAVID (France), Mr Jaman ÖRS (Turkey), Mr Daniel SERRÃO (Portugal) and Mr Peter THOMPSON (United Kingdom).

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 Mr Örn BJARNASON (Iceland), extended terms of reference to examine the draft Protocol on transplantation in the light of the Convention provisions.

7. The current draft Protocol was examined by to the CDBI on its 15th meeting (7-10 December 1998). It was declassified by the Committee of Ministers on ... .

8. 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 .... 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.

Comments on the provisions of the Protocol

Title

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

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

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[2] Membership of the CDBI-CO-GT1: Mr Örn BJARNASON (Iceland), Mr Peter DOYLE (United Kingdom), Ms Isabelle ERNY (France), Mr Radkin HONZÁK (Czech Republic), Ms Blanca MIRANDA (Spain), M. Lars-Christoph NICKEL (Germany) and Mr Ergün ÖZSUNAY (Turkey).

Preamble

11. 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 and important 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. It also highlights the fact that Article 1 of the Convention on Human Rights and Biomedicine protecting the dignity, the identity and the integrity of all persons 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.

12. 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.

Chapter I
(Object and definitions)

Article 1 (Object)

13. 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.

14. The term "everyone" is used in Article 1 because it is seen as the most concordant with the exclusion of embryonic or foetal organs or tissues from the scope of the Protocol as stated in Article 2. The Protocol solely concerns removal from someone who has been born, whether living or dead, and implantation into someone who has likewise been born.

Article 2 (Scope and definitions)

15. This article sets out the scope of the Protocol and of transplantation of organs and tissues of human origin, and defines the main terms used.

Scope

16. The Protocol applies solely to the transplantation of human organs and tissue and therefore not 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 so it seemed advisable to place them outside the protocol's scope.

17. Blood and its derivatives are excluded from the Protocol as they have for many years been used for different therapeutic purposes; furthermore, transfusion is subject to specific regulations. However, as the harvesting of peripheral stem cells, and in particular haemopoietic cells, requires stimulatory treatment of the donor's bone marrow, it has been agreed that this type of transplant comes within the scope of the Protocol.

18. Reproductive organs and tissue (comprising ova, sperm and their precursors) are also 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.

19. 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.

20. Finally, the Protocol does not cover the pharmaceutical products which have been derived from removed organs or tissues.

Definitions

21. 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.

22. 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". 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 regrow 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.

23. The Protocol sets out to overcome this difficulty by using the terms "organs" and "tissues" throughout the text, except in Article 9 (see paragraphs 24 and 25 above), so that all provisions apply to all parts of the body. The term "tissue" includes cells (excepted those specifically excluded) ; cell transplantation is an ever more widely used procedure and must therefore be governed by this Protocol.

24. It is nevertheless possible to distinguish between on the one hand main organs or parts of organs e.g. heart, lungs, liver, kidney, pancreas, bowel and on the other hand, tissues 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 such "organs" may differ from those applying to tissues and cells.

25. 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 or cells from a living donor generally carries a low risk of harm. These differences justify that the rules are also different; for this reason Article 9 deals with the specific case of organ removal from a living person.

26. For the purposes of this Protocol, the term "organ" is accordingly applied to vital organs or parts of vital organs which require a major surgical procedure for removal and which need to be transplanted rapidly. The term "tissues" covers all other those parts of the body, including cells, not specifically excluded.

27. 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 the donor and the person into whom the material is implanted is the 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 donor 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.

28. The provisions of this Protocol concerning removal apply if its purpose is transplantation. Removal of tissue carried out for any other purpose, as for the placenta, is not covered by the Protocol. Nevertheless, as stated in Article 18, when in the course of an intervention an organ or tissue is removed for a purpose other than donation for implantation, it may be transplanted only if this is done in conformity with appropriate information and consent procedures (see paragraphs 91 to 94 above). 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)

29. 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 are 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.

30. Those requirements 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 organ transplantation and to transplant waiting lists.

31. The transplantation system should also ensure that organ allocation is according to rules which are both transparent and duly justified. Transparency requires that the allocation criteria are open and understandable. The criteria used must also be justified in terms of fairness, accuracy and reproducibility and conform with the ethical principles enshrined in the Convention on Human Rights and Biomedicine. For example, medical criteria such as tissue matching which affect the likelihood of success of the transplant will be arguably the most important criteria but other factors such as time on the waiting list may have to be included if allocation is to be seen to be fair. Particularly difficult are decisions about eligibility of the recipient for which some definition of citizenship or residence shall be taken into account. Additionally, people should not be allowed to be on more than one transplant waiting list as this will prevent access by others. 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.

32. In order to ensure the allocation rules are transparent and well-founded, they should 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.

33. 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 latter in a recipient, donors would have to be traced to identify the one who transmitted the disease and unused products withdrawn. 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 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.

Article 4 (Professional standards and medical indications)

34. 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.

35. 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.

36. 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.

37. A doctor's, or other health care worker's, competence 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 donor, e.g. lymphoma or graft versus host disease, and such considerations should also be taken into account and the safest transplantation technique used.

38. Professional obligations 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.

Article 5 (Information for the recipient)

39. This article sets forth the recipient's right to be properly informed prior to implantation. Even though a transplant is normally 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. 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)

40. 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. Furthermore, 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. It may very occasionally be acceptable to transmit a disease if the alternative is certain death. Equally it might be acceptable to implant an organ or tissue affected by some infectious diseases such as CMV (Cytomegalovirus) if the recipient already suffers from the same pathology, or the appropriate preventive measures have been started.

41. 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 example : for hepatitis C virus, the recipient can carry it and never develop the disease).

42. 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 transmitted with 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.

43. 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 appropriate consent has been given.

44. 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 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.

45. It is the responsibility of the persons involved in the removal of organs from potential donors 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.

46. Those involved in the transport of organs and the preservation and storage of tissues 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 19.

Article 7 (Information for health professionals and the public)

47. It is for States Parties to the Protocol to ensure that adequate and 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 legal, social, ethical and other issues concerned. 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. The position is constantly changing so the provision of information is an ongoing responsibility, not just an occasional one.

48. 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.

Chapter III
(Organ and tissue removal from living persons)

Article 8 (General rule)

49. According to the first principle set out in the text, organs or tissues should be removed from deceased donors rather than from living donors whenever possible. Removing organs or tissues from living donors always carries some risk for that donor, if only because of the anaesthesia they sometimes have to undergo. 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.

50. 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 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.

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

Article 9 (Potential donors)

52. 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. As removal of an organ from a living person must be performed only in circumstances where cadaveric transplant is not an equivalent therapeutic option (Article 8), it defines those circumstances in which living donation of an organ is acceptable.

53. Those circumstances normally require that an appropriate relationship 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, but it would normally be expected to be close. The intention is to prevent undue pressure to donate being brought to bear on people without a strong emotional relationship with the recipient. Those with an appropriate relationship with the recipient may include members of the recipient's immediate family, parents, brothers, sisters, spouses or long-standing partners, godparents or close personal friends. It is very difficult to frame a law or rule which properly defines all those who may have a good reason for wishing to donate. Many countries have laws defining the nature of the relationship which is required to exist between donor and recipient and which makes live donation acceptable. However, to allow for the variety of situations and countries without such laws, an independent body may give approval for live donation. This is an important safeguard against potential organ trafficking or the use of inducements.

54. Under the terms of this Protocol, living donation must remain an exceptional procedure. However, there is some evidence that despite the risks incurred, there may be perceptible long-term psychological benefit to organ donors who, even if not a closely related, have helped improve the health or even save the life of a recipient. In such circumstances, an independent body, for example an ethics committee, should consider such cases and, if appropriate, give approval.

55. The independent body required under this Article is not the same as the official body identified in Article 13. The two bodies have different responsibilities.

56. 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 applicable.

Article 10 (Evaluation of risks for the donor)

57. 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 to be fully assessed.

58. 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.

59. 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. Of these, the first two are more properly covered by the articles on consent : consent should not be given for donation if the risk is considered to be unacceptable. 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. 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. 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 11 (Information for the donor)

60. 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 also requires the supply of information to the representative, authority, person or body providing authorisation according to Article 13.2 of this Protocol.

61. 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 it must be given prior to consent 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. The donor must be given adequate time to fully consider the information provided and discuss it with friends and/or relatives. If the donation requires an authorising party under Article 13.2 those discussions will normally include the potential donor.

62. 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 and 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 and can be requested by the donor if he/she wishes. However, that person must have appropriate experience of the risks associated with donation and transplantation to be able to give proper advice. An authorising party under Article 13.2 should have the same access to independent advice.

Article 12 (Consent of the living donor)

63. 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 indue pressure on the donor, he should be assured that he/she can refuse to donate or withdraw his/her consent at any time in complete confidence.

64. 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 Article 13 of this Protocol.

65. 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 be also specific and given in written form or before an official body.

66. The freedom to withdraw consent at any time set out in the second paragraph has to be respected, and there is no requirement for withdrawal of consent to be in writing or to follow any particular form. The donor need simply say no at any time, even if a procedure performed under local anaesthetic has commenced, unless the circumstances are such that to stop the procedure would be a greater risk to the patient than its completion. Article 13 affords the same protection to donors of regenerative tissue lacking capacity to consent to their removal.

Article 13 (Protection of persons not able to consent to organ removal)

67. Provisions relating to consent to organ or tissue removal for transplantation 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.

68. Article 13 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 13 follows the wording of Article 20 of the Convention.

69. 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.

70. 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.

71. 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 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 8 also apply.

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

73. 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.

74. 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.

75. 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 body provided for by law is needed before the removal can be carried out. 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.

76. 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.

Chapter IV
(Organ and tissue removal from deceased persons)

Article 14 (Promotion of donation)

77. Shortage of cadaveric organs will increase the pressure to perform live donations and the possibility that desperate people may try to find other ways of obtaining a transplanted organ. As transplantation using cadaveric organs and tissues is the preferred option, this article lays an obligation on all Parties to take all appropriate measures to promote organ procurement from deceased persons.

78. The "appropriate" measures are not defined but will include the provisions on information to be provided to health professionals and to the public (Article 7), the need to set up a transplant system (Article 3) and to have recognised means of giving consent or authorisation (Article 16).

79. It is also implicit in this article that organ removal from deceased persons has to be given priority if living donation is to be minimised. However, organ removal from deceased persons must itself carry safeguards and these are set out in the following articles.

Article 15 (Certification of death)

80. 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 of 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.

81. The death is confirmed by doctors following an agreed procedure and only this form of death certification can permit the transplantation to go ahead. In some States, this procedure for certification of death is separate from the formal issuance of the death certificate.

82. The second paragraph of Article 15 provides an important safeguard for the potential donor by prescribing that the medical team which certifies death should not be the same one that is involved in any way with the transplant process, either the removal or subsequent stages. It is important that the interests of any potential donor 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 and therefore potential donors' trust in the transplantation system and might have an adverse effect on donation.

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

Article 16 (Consent and authorisation)

84. Article 16 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.

85. 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.

86. 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.

87. 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 relations and friends to establish whether or not the deceased person was in favour of organ donation.

88. 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. The close relatives are to 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.

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

Article 17 (Respect of the human body)

90. A dead body is not legally regarded as a person, but nonetheless should be treated with respect. This Article accordingly provides that when organs or tissues are removed from a deceased person, the removal should be done with dignity and after removal the body should be restored as far as possible to its original appearance.

Chapter V
Disposal of a removed organ or tissue

Article 18 (Disposal of a removed organ or tissue)

91. 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. The first recipient then 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 recipients heart and be transplanted into a third person. Another example of removal for purposes other than donation for implantation is when a functional kidney has to be removed for some reason such as disease affecting the urinary tract. If the patient's other kidney is fully functional there is no point in trying to re-implant the kidney but it could be implanted into another person.

92. This Article is also applicable where, in the course of an intervention, tissues are removed then processed and re-implanted into someone else. It this case, the person undergoing the intervention must consent to the use of these tissues, even if they are regarded as discarded tissues at the time of the intervention. This provision also ensures the traceability of the tissues.

93. In such cases it is still essential to obtain appropriate consent from the recipient or the competent person or body for the use of the organ or tissue for transplantation. The first recipient of a heart can be a child. In turn his/her heart or the valves which are removed can be implanted in an other child, if the persons providing authorisation have agreed after being duly informed.

94. States are free to arrange the procedures for information and consent or authorisation as each case may require but consistent in the provisions of this Protocol.

Chapter VI
(Prohibition of financial gain)

Article 19 (Prohibition of financial gain)

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

96. 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 comparable to a financial gain such as benefits in kind, promotion or preferment. A third party involved in the transplant process such as a tissue bank may not make a profit from organs or tissues or any products developed from them (but see paragraph 98 below).

97. However, Article 19 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.

98. 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, preservation and storage of organs or tissues which will have to be recovered. Cost recovery must be made within reasonable limits.

99. 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 22.

100. 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 and States will be expected to provide appropriate penalties.

101. The provision refers solely to organs and tissues covered by the Protocol and not to such human products as hair, nails or teeth which, being discarded tissues, can be sold without any affront to human dignity.

Chapter VII
(Confidentiality)

Article 20 (Confidentiality)

102. Article 20 lays down the principle of confidentiality. Preserving the anonymity of the donor may be impossible in certain circumstances, for example because of the requirement of an appropriate relation between the donor and the recipient in the case of living organ donation. However, personal data concerning donors and recipients must nonetheless be treated as confidential and handled in accordance with the rules on privacy. 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) and other instruments on the subject 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*".

103. 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 donor and recipient, and keeping track of the exchange of organs or tissues between them. One organ donor may in fact supply several organs or tissues to be implanted in more than one recipient. If a disease is subsequently detected in a donor, the recipients must be traceable. Equally, if a recipient of a transplant develops a disease which may have been transmitted, the donor 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.

Chapter VIII
(Infringements of the provisions of the protocol)

Article 21 (Infringements of rights or principles)

104. 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.

105. 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.

106. 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.

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

Article 22 (Compensation for undue damage)

108. This Article sets forth the principle that any 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.

109. 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.

110. 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.

111. 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.

112. Article 19 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 23 (Sanctions)

113. Since the aim of the sanctions provided for in Article 23 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 24 (Co-operation between parties)

114. 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.

115. 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.

Chapter X
(Final provisions)

Article 25 (Relation between the Convention and the Protocol)

116. 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.

117. 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.

Article 26 (Signature and ratification)

118. 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.