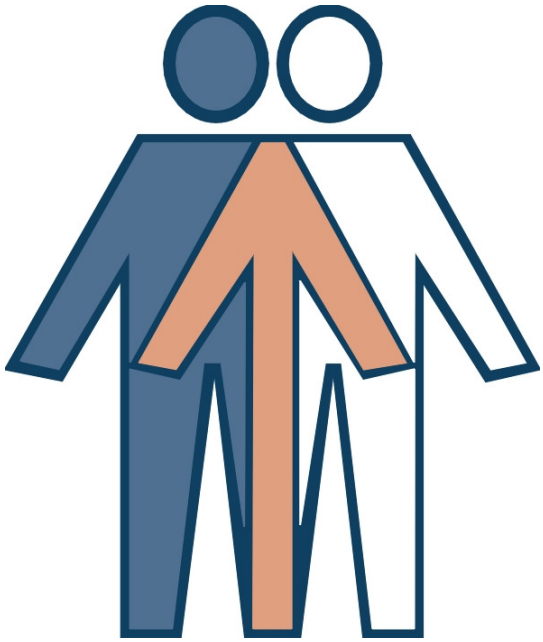

# EUROTRANSPLANT

# MANUAL


## Eurotransplant Foundation

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# Eurotransplant Manual

# Change record

| Date | Author | Version | Change reference |
|---|---|---|---|
| 26-03-2012 | C.M. Tieken | 3.0 | Adjustment of 1.2.2.2 The board and 1.4.2 Ethical considerations |
| 22-04-2011 | C.M. Tieken | 2.0 | Adjustment of Articles of Association |
| 25-02-2011 | C.M. Tieken | 1.3 | Change name selection system in allocation system and medical criteria in medical and ethical criteria |
| 07-06-2010 | J. de Boer | 1.2 | Change name Advisory Committee: Computer Services Working Group into Information Services Working Group |
| 17-02-2010 | C.M. Tieken | 1.1 | 1.2.2.4 organization chart |
| 24-03-2009 | C.M. Tieken | 1.0 | 1.2 organization charts 1.3 Joint declaration |

# Chapter 1 – Introduction Table of contents

## Introduction

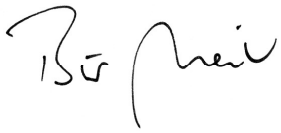
It is with great honor and pride that we present to you the Eurotransplant Manual. The ET manual is constantly being revised and updated and is available electronically in the Members' Library at www.eurotransplant.org. The manual is an expression of a collaborative effort for which we are all responsible.

We hope that this manual will be a help whenever a quick reference to ET guidelines and procedures is needed, and therefore will frequently be consulted by physicians, transplant coordinators and all involved in transplantation within Eurotransplant. It is allowed and encouraged to quote this manual on the condition that the source and version dates are clearly indicated.

No rights can be derived from the ET manual; this can only be done from accepted recommendations by the ET Board, which are published in the ET Newsletter. The manual is updated on a regular basis each time that the ET Board decides to change the rules.

We would like to use this opportunity to thank you for your continuous support. Such help would certainly include also criticism, which is the most effective form of support.

Leiden,
September 29, 2006



Dr. B. Meiser
President

A. Oosterlee, MBA
General Director

Dr. A. Rahmel
Medical Director

## 1.1 Eurotransplant – From multicenter trial to international foundation

In 1967, the concept that optimal tissue typing and matching between donor and recipient would improve results of renal transplantation was proposed by prof. Jon J. van Rood, immunologist at the Leiden University Medical Center. At his initiative, an international collaboration between transplant centers, donor hospitals and tissue typing laboratories began, centrally coordinated by the Eurotransplant International Foundation, also known as Eurotransplant. Founding member countries were Austria, Belgium, Germany, Luxembourg and the Netherlands. Ever since its conception, Eurotransplant continuously proved that the initial concept was accurate, providing the cornerstone for this unique and truly European collaboration based on free will, trust, solidarity and consensus amongst clinicians in this field.

Eurotransplant's primary goals have been, and continue to be, to secure through effective and efficient allocation the optimal use of scarce donor organs. And even until today, transplant results in kidney transplantation greatly depend on matching of tissue typings between donors and recipients.
Following the early activities in the field of renal transplantation, the other solid organs would soon become part of daily transplantation and, thus, allocation practice. This was in great part due to the introduction of new and more potent immunosuppressive drugs, starting with Cyclosporin in the 1980s. As a consequence, transplant physicians pioneered into liver, heart, pancreas (islets), lungs, hepatocytes, and, finally, intestine transplantation.

The 1990s were greatly marked by the fall of the Berlin wall, when the former East Germany was incorporated into Eurotransplant and the implementation of new and more powerful computers supporting the Eurotransplant staff in managing the ever increasing waiting lists. A next step was the official acknowledgement of this European collaboration in organ donation, allocation and transplantation, as a Joint Declaration was signed by the Health Ministers of the six ET member countries in 2000.

With the concept of collective effort and benefit holding true, Slovenia was welcomed in January 2000 as the sixth participant, the first new member since the Eurotransplant's foundation. In July 2006, the Republic of Croatia began its candidate membership, resulting in a permanent membership in May 2007.

Today, Eurotransplant is a well established, ISO 9002-certified logistical organization, operating 24/7. Its main task, in a joint effort, is to apply scientific and technical progress for the future benefit of any individual transplant candidate. Eurotransplant's innovative ambition was exemplified through the successful implementation of the Acceptable Mismatch (AM) (1996) and the Eurotransplant Senior Program (ESP) (1999), both for the kidney. Participation in multicenter trials, e.g. conducted by Organ Recovery Systems (ORS) in 2005/2006, is another of the many services Eurotransplant offers to its members.

Together with its partners Eurotransplant continues to play a key role in these difficult times of an ever increasing gap between patients awaiting organ transplantation and the lack of sufficient post-mortem donor organ, serving patients in six European countries with over 120 million inhabitants.

## 1.2 The Eurotransplant concept

Eurotransplant (ET) is an international, non-profit organ exchange organization whose is responsible for the allocation and international exchange of post-mortem donor organs. ET coordinates donation procedures across a region with over 120 million inhabitants, providing services to transplant centers, tissue typing laboratories and donor hospitals in Austria, Belgium, Germany, Luxembourg, the Netherlands, Slovenia and Croatia.

### 1.2.1 Mission statement and goals

Mission

- Service organization for transplant candidates through the collaborating transplant programs within the organization.

Goals

- Realize an optimal use of available donor organs and tissues.
- Secure a transparent and objective allocation system based on medical and ethical criteria.
- Assess the importance of factors that have the greatest influence on transplant results.
- Support donor procurement as to increase the supply of donor organs and tissue.
- Further improve the results of transplantation through scientific research.
- Promote, support and coordinate organ transplantation in the broadest sense.

#### *1.2.1.1 Methods*

As mediator between donor and patient, Eurotransplant plays a key role in the management of the distribution of donor organs for transplantation. The data of all potential recipients, such as AB0 blood group, tissue characteristics (HLA groups), primary disease and clinical urgency, are passed on to Eurotransplant. This information is stored in a central computer database. Subsequently, depending on the needs of this patient, he is put on one or more of the organ-specific (inter)national waiting lists.

From that moment on waiting time starts, with the exception of patients on the kidney waiting list, whose waiting time starts on the first day of dialysis. As soon as a donor is available anywhere within the Eurotransplant area, the regional tissue typing laboratory determines the donor's blood group and tissue characteristics. All relevant (medical) information about the donor is then transferred to Eurotransplant database either by fax or electronically applying up-to-date technology.

Subsequently, after all donor data was entered, the matching programs are started to select the most suitable patients for the available organs.

Allocation criteria can vary for the different donor organs:

| Organ | Allocation criteria |
|---|---|
| Kidney | Blood group, tissue characteristics, clinical urgency, waiting time |
| Pancreas | Blood group, (tissue characteristics), clinical urgency, waiting time |

| Organ | Allocation criteria |
|---|---|
| Heart + Lung | Blood group, size of the donor, clinical urgency, waiting time |
| Liver | Blood group, size of the donor, clinical urgency, waiting time |
| Intestine | Blood group, age and size of the donor, clinical urgency, waiting time |

After completing the matching procedure, Eurotransplant immediately contacts the physicians in the patient's transplant center to make the offer and to provide all donor information. These physicians then have to decide on the offer, i.e. whether or not to accept the organ. In case of accepting the organ, the physician immediately contacts the patient.

As soon as the donor organ has been accepted, Eurotransplant, in cooperation with the regional transplant coordinator, arranges for the organs to be procured. At the same time, the (international) transportation of the organs from the donor hospital to the recipients in the transplant hospitals is organized. If there are no suitable recipients within the Eurotransplant area, Eurotransplant gets in touch with one of its European sister organizations.

The whole process from organ procurement to the recipient's transplantation must not take longer than a few hours, depending on the organ concerned. An impeccably smooth running organization is thus literally of life-saving importance. Hence the Eurotransplant central office is manned 24/7 by specially trained staff, together with indispensable support by, among others, physicians, the police, ambulance services and airline companies in the Eurotransplant region.

#### *1.2.1.2 Science*

After the recipient has undergone his transplantation, Eurotransplant remains in touch with the transplant center in order to be kept informed about the outcome. Analyses of these data may help indicate factors which influence the transplantation result in the longer term. Such factors could then lead e.g. to the modification of allocation factors in matching procedures aiming at the finding the most suitable patients. Among these factors are the various tissue characteristics, the organ preservation techniques, donor and recipient age and immunosuppressive agents counteracting the rejection of the transplanted organ.

### 1.2.2 Organizational structure

ET is operated by the central office in Leiden, the Netherlands, and is composed of the Assembly, the Board of Management, the Board of Directors and the Advisory Committees (see Addenda 1.5.1, Articles of Association).

#### *1.2.2.1 The Assembly*

All individual transplant centers are represented in the Assembly. Each transplant program may delegate one representative. In centers with more than 1 transplant program, more representatives can be delegated. The Assembly members have voting power, which is related to the number of transplants performed in the previous year. The Assembly is subdivided into organ specific sections for kidney, heart & lung, liver/intestine, pancreas/islets and the tissue typers.

*1.2.2.2 The Board*

ET is managed by a general board consisting of a maximum of 22 members, of which:

- 10 are elected by and from the Assembly (A);
- 6 members are elected in virtue of their organization (chairmen of the 5 national transplant societies(B)
- 1 head of the ET Reference Laboratory (C);
- 2 members are elected by the Board (financial and ethics experts) on personal basis (D);
- 1 President;
- 1 member can be elected by the Board as Past-President.
- 1 observer from Hungary

For details see Addenda, Articles of Association (1.5.1).

*1.2.2.3 Advisory Committees*

1.2.2.3.1 Organ-specific Advisory Committees

Organ specific Advisory Committees evaluate rules regarding procurement, preservation, allocation and transplantation, and are advisory to the Board. The following committees exist:

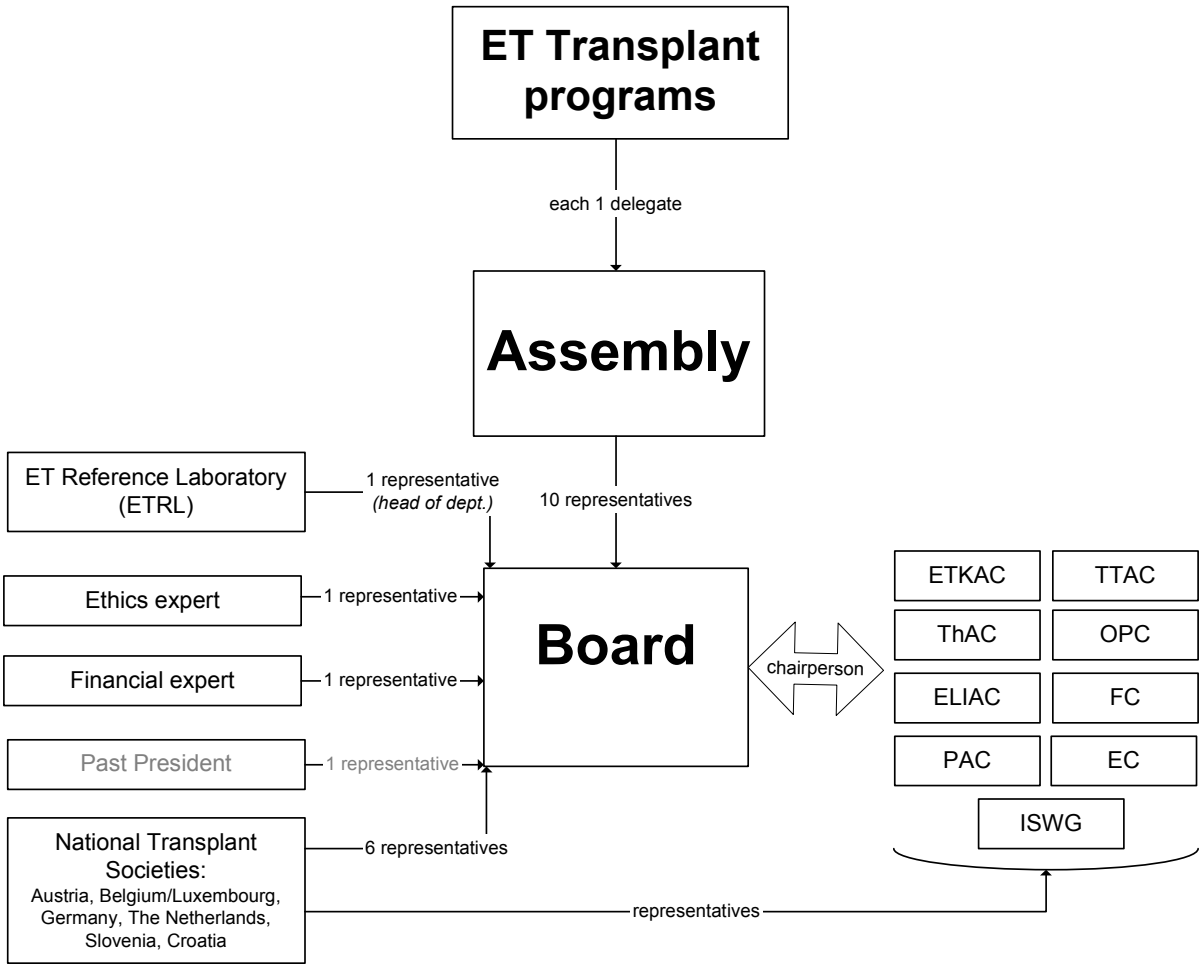
- Kidney Advisory Committee (ETKAC)
- Thoracic Advisory Committee (EThAC)
- Liver Intestine Advisory Committee (ELIAC)
- Pancreas Advisory Committee (EPAC)

1.2.2.3.2 Other Advisory Committees

- Tissue Typing Advisory Committee (TTAC): advises the Board on any aspect concerning tissue typing activities in Eurotransplant.
- Organ Procurement Committee (OPC): advises the Board on any aspect of and formulates standards for donor management, organ procurement, and stimulates education of the medical profession.
- Financial Committee (FC): advises on any financial matter of the foundation.
- Ethics Committee (EC): advises the Board on any ethical aspect involving the foundation.
- Information Services Working Group (ISWG): sets recommendations and evaluates proposals with respect to the development of the ET Network Information System (ENIS).

For further information see Articles of Association (1.5.1).

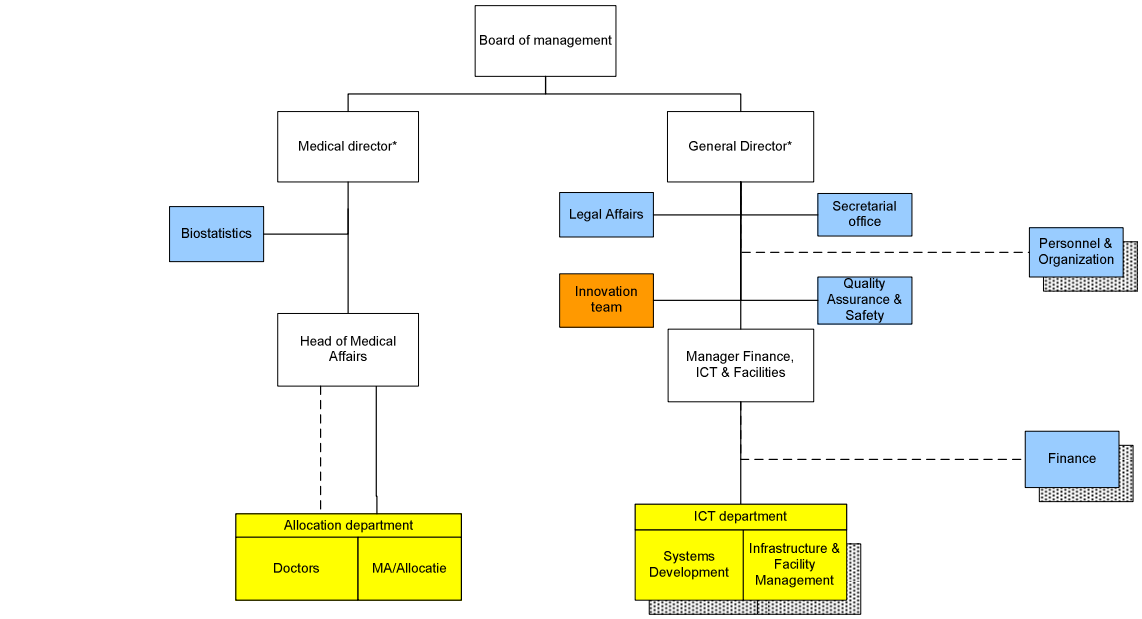
### 1.2.2.4 Organizational chart - Eurotransplant



### 1.2.3 Eurotransplant office

ET is an administrative organization, established to service all participating transplant centers and associated tissue typing laboratories. The day-to-day management of the office is the responsibility of the directors, which are appointed by the Board.

#### *1.2.3.1 Organizational chart – ET central office*




The dotted lines indicate the functional relationship between manager and shared services departments, which are managed by either BIS or NTS.
The solid lines indicate the hierarchical relations
The ICT department is a shared services department managed bij Eurotransplant

* The Board of directors consists of the General Director and the Medical Director
- General Director: General management
- Medical Director: Management medical affairs

** Primus inter pares

Department
Staff
Permanent committee

### 1.2.4 Eurotransplant Manual

The Eurotransplant Manual, as published and accessible through the member's site at www.eurotransplant.org contains the official rules and regulations for waiting list management, organ donation and allocation in Eurotransplant. These regulations must be followed by all ET users[1].

[1] RET01.05 accepted by the ET Board on January 19, 2005.

### 1.2.5 Eurotransplant Network Information System (ENIS) Manual

The Eurotransplant Network Information System (ENIS) Manual, as published and accessible through the member's site at www.eurotransplant.org contains the official rules and regulations for remote users of ENIS. These regulations must be followed by all ET users[2].

### 1.2.6 Financing

ET is financed by the health insurance companies from the participating ET countries. The budget for the Eurotransplant International Foundation is submitted to and approved by the Board. Subsequently, the budget has to be negotiated with the relevant health authorities in the different ET countries.

All ET activities generate costs, which are financed through the budget. These costs are paid for by the revenues resulting from the patients' registration fees. These fees can differ per organ and country. Differences between registration fees in the various ET countries are a result of the extent of services provided to an ET country. The registration fee is calculated by dividing the approved annual budget by the total number of expected new registrations, and is therefore adjusted annually. The registration fee must be paid for each new or re-registration of a patient on any organ waiting list.

In addition, ET has a so-called clearing-house function for some donor related activities. ET reimburses the costs for the *explantation procedure* and *the donor related transport costs* to the organizations concerned as soon as the invoices are received and checked.

Explantation costs are costs which are paid to the donor procurement team and donor hospital to cover costs for donor procedures. Transport costs include the costs for transporting blood samples for testing, the travel costs of procurement teams and transport of organs.

### 1.2.7 Membership

ET is a cooperation of transplant centers and tissue typing laboratories. A transplant center is an institution which performs organ transplantations and which is entitled to an ET center code, provided that the respective national health authority approved of the program. A tissue-typing center is a laboratory performing tissue typings.

The cooperation between ET and the individual transplant centers or tissue typing laboratories is based upon agreements with health insurance organizations and a consensus document signed by the Health Ministers of the six ET member countries (see 1.3).

The policy statement Eurotransplant computer system (see Addenda, 1.5.3) is applicable to all transplant centers.

In addition, contractual agreements have been established with a number of official organizations, among which are:

- Belgium
  - Belgische Transplantatieraad (Belgian Transplant Council)
- Germany
  - Bundesärztekammer (BÄK)
  - Deutsche Krankenhausgesellschaft (DKG)
  - Verband der Angestellten-Krankenkassen (VdAK)
  - Deutsche Stiftung Organtransplantation (DSO)
- The Netherlands
  - Nederlandse Transplantatie Stichting (NTS)
- Slovenia
  - Slovenija Transplant
- Austria
  - Austrotransplant
- Croatia
  - Ministry of Health and Social Welfare

#### *1.2.7.1 Candidate membership*

Countries can apply for a candidate membership. If agreed between both partners, this candidate membership can be converted to a permanent membership after an evaluation period.

For terms and conditions countries should approach the Board of Directors in writing.

### 1.2.8 Application of new transplant programs or centers

Transplant programs (or centers) applying for a new ET center code can only be accepted under the following conditions. The transplant center needs permission:

- of the hospital's board;
- of the local or national government, if required by national legislation;
- of non-governmental institutions, if required by national legislation (e.g. health insurance organizations).

A center code can only be assigned upon submission of these permissions in writing to the directors of ET.

### 1.2.9 Collaboration between programs/centers

An intended co-operation between programs/centers within ET and/or outside ET should be sent to the ET Directors in writing, signed by the respective heads of departments for approval. The ET Directors will evaluate such initiative and its consequences, and if it is in accordance with existing allocation rules and/or Articles of Association.

## 1.3 Joint declaration regarding cooperation within the framework of Eurotransplant International Foundation

The Minister of Consumer Affairs, Public Health and Environment of the Kingdom of Belgium,
The Federal Minister of Health of the Federal Republic of Germany,
The Minister of Health of the Grand Duchy Luxembourg,
The Minister of Health, Welfare and Sport of the Kingdom of the Netherlands,
The Federal Minister of Labour, Health and Social Affairs of the Republic of Austria,
The Minister of Health of the Republic of Slovenia, and
The Minister of Health and Social Welfare of Croatia,

issue the following joint declaration regarding cooperation within the framework of Eurotransplant International Foundation

### 1.3.1 Introduction

As ministers of health we express our appreciation of the activities of Eurotransplant International Foundation (ETI) in Leiden, the Netherlands. ETI is a foundation that has arisen from private initiative. We take the view:

- that the importance of international cooperation on organ transplantation within the ETI framework has been demonstrated and should be continued;
- that distribution of the allocated donor organs as fairly as possible within a transparent and objective allocation system according to medical criteria is crucial for the acceptance of transplantation medicine in the participating countries;
- that a less voluntary form of cooperation on organ exchange within the ETI framework is necessary to retain public confidence and to bring about the required strengthening in ETI's position;
- that government responsibility within the existing regulatory framework for this area is unequivocal, as witnessed also by the legislation passed in the various countries recently;
- that the time is ripe to shape government involvement, also given the background of a possible broadening in cooperation within the ETI framework;
- that there is a need for ETI to be strengthened and for a clear and unambiguous framework for ETI to operate within, as this will enable it to perform its duties responsibly.

### 1.3.2 Framework

Given the above, we have agreed on the following framework. It incorporates the criteria that are essential for ETI to continue to operate responsibly and has the following components:

- objective allocation system according to medical criteria;
- safety and quality requirements;
- transparency and follow-up;
- government involvement.

### 1.3.3 Framework details

An objective allocation system according to medical criteria.
All post-mortem organs that become available for implantation (donor organs) in the participating countries are - taking account the respective domestic legislation - reported to ETI[2]. Using the allocation criteria arrived at on the basis of consensus, ETI's task is to ensure optimum allocation of the donor organs. The donor organs are allocated according to the following criteria:

- the most important factor is to maximize equality of opportunity for patients, and to do so by taking into account objective medical criteria (e.g. compatibility of organ with recipient, the expected transplantation result, medical urgency and how long a recipient has been waiting) as well as individual differences;
- the allocation system must be patient oriented;
- the allocation procedures must be transparent and objective;

Procedures must ensure justified, genuine distribution across the participating countries in a manner that takes account of the solidarity principle within each country. The objective is transparency of the medical criteria applied to transplantation and the moment of registration on the waiting list. The placing of patients on the waiting list and the determination of the criteria applied here are matters primarily for the doctors concerned and must take place in accordance with the most recent advances in medical science.

Safety and quality requirements
The state of a donor organ eligible for allocation by ETI must comply with those safety and quality requirements that can be imposed in accordance with the most recent advances in medical science. ETI must ensure that they do so comply.

Transparency and follow-up
Given the need for the allocation procedures to be transparent and objective, government in the participating countries must receive current and reliable information periodically - and, if necessary, on request - in order to facilitate monitoring of the entire organ allocation process and ensure that the allocation criteria and the safety and quality requirements are being applied.

Government involvement
This involvement will be constituted by ETI's answerability to government in the participating countries under conditions still to be elaborated; these will include a periodic evaluation of how ETI is working.

[2] Within the framework of twinning agreements between participating countries' transplantation centers and similar institutions in other countries, the same principles are applied as those included in the present document.

### 1.3.4 Action items

Given the above considerations and the need to take account of national regulatory frameworks, as well as the efforts directed at the implementation of appropriate measures to improve the existing opportunities for post-mortem organ donation, we as ministers of health:

- promote the reporting within the respective domestic regulatory frameworks of all donor organs to ETI as the organization responsible - on the basis of the allocation criteria arrived at by consensus - for ensuring optimum allocation of donor organs;
- request ETI - assuming a patient oriented allocation system within the respective domestic regulatory frameworks, in cooperation with experts and in line with the most recent advances in medical science - to present to government in the participating countries a set of basic principles for organ allocation internationally;
- agree with ETI on what information, in what form, and how, government in the participating countries is to be supplied with;
- enter discussion with ETI on how to shape government involvement;
- promote discussion with and between the expert and professional organizations (in the first instance medical professional organizations) in the participating countries in order to achieve further clarity for patients eligible for transplantation;
- request that ETI, operating according to the general principles and criteria specified in this document, cooperates with experts from the participating countries and, in close consultation with them, generates directives for the twinning agreements between the transplantation centers in the participating countries and similar institutions in other countries.

This declaration was signed in November 2000 by:

Brussels, The Minister of Consumer Affairs, Public Health and Environment of the *Kingdom of Belgium,*

Magda Aelvoet

Bonn, The Federal Minister of Health of the *Federal Republic of Germany,*

Andrea Fischer

Luxembourg, The Minister of Health of the *Grand Duchy of Luxembourg,*

Georges Wohlfahrt

The Hague, The Minister of Health, Welfare and Sport of the *Kingdom of the Netherlands,*

Els Borst-Eilers

Vienna, The Federal Minister of Labour, Health and Social Affairs of the *Republic of Austria,*

Lore Hostasch

Ljubljana, The Minister of Health of the *Republic of Slovenia,*

Andrej Brucan

On September 24, 2007 during the Eurotransplant Foundation Ministers conference an additional declaration was signed in Valkenburg aan de Geul.

Joint Declaration on cooperation within the framework of Eurotransplant International Foundation

The Minister of Social Affairs and Public Health of the Kingdom of Belgium,

The Minister of Health and Social Welfare of the Republic of Croatia,

The Federal Minister of Health of the Federal Republic of Germany,

The Minister of Health and Social Security of the Grand Duchy Luxembourg,

The Minister of Health, Welfare and Sport of the Kingdom of the Netherlands,

The Federal Minister of Health, Family and Youth of the Republic of Austria
and
The Minister of Health of the Republic of Slovenija,

issue the following Joint Declaration on cooperation within the framework of Eurotransplant International Foundation:

We, Ministers of Health, wish to express our recognition of the activities performed by the Eurotransplant International Foundation (ETI) in Leiden, the Netherlands.

We are of the opinion that the subjects addressed in the Joint Declaration of November 2000 are today undiminished valid.

We emphasize:

- that the importance of international cooperation on organ transplantation within the Eurotransplant International Foundation framework has been demonstrated and should be continued;
- the necessity and added value of a fruitful cooperation between the professionals and the national authorities within the framework of Eurotransplant as opposed to separate agreements;
- that it is of crucial importance for the acceptance of transplantation medicine in the participating countries and in the interest of the patients that distribution of the allocated donor organs is performed as fairly as possible within a transparent and objective allocation system according to medical criteria;
- the necessity of having systems operational for quality and safety in the area of organ donation. The state of a donor organ eligible to be allocated by Eurotransplant International Foundation must comply with those safety and quality requirements that are or might be imposed in accordance with the most recent advancements in medical science.
- our involvement as Ministers of Health with Eurotransplant International Foundation, its transparent and unambiguous allocation system and the responsibility of Eurotransplant International Foundation towards the participating member states.

Given the above considerations and the need to take into account national regulatory frameworks as well as efforts directed at the implementation of appropriate measures to improve the existing opportunities for post-mortem organ donation, we, Ministers of Health

- agree that the mutual exchange of practices in the area of post-mortem organ donation between the Eurotransplant International Foundation member states is valuable and supported by us;
- agree that Eurotransplant International Foundation fulfils an important role as a platform for the exchange of knowledge and practices;
- encourage the realization of a collection system for transplant results within Eurotransplant International Foundation.

*This declaration was signed on September 24, 2007 in Valkenburg aan de Geul, the Netherlands:*

on behalf of the Minister of Social Affairs and Public Health of the Kingdom of Belgium,
President of the Board of Directors of the Federal Public Service Health, Food Chain, Safety and Environment

*Dr. Dirk Cuypers*

The Minister of Health and Social Welfare of the Republic of Croatia,

*Prof. Dr. Neven Ljubičić*

The Federal Minister of Health of the Federal Republic of Germany,

*Mrs. Ulla Schmidt*

The Minister of Health and Social Security of the Grand Duchy of Luxembourg,

*Mr. Mars di Bartolomeo*

The Minister of Health, Welfare and Sport of the Kingdom of the Netherlands,

*Dr. Ab Klink*

Vienna, The Federal Minister of Health, Family and Youth of the Republic of Austria,

*Dr. Andrea Kdolsky*

The Minister of Health of the Republic of Slovenija,

*Mrs. Zofija Mazej Kukovič*

## 1.4 Legal and ethical considerations in Eurotransplant

### 1.4.1 Legislation

Currently, most countries within Eurotransplant have legislation in the area of organ donation. This reflects the national public interest in caring for their transplant patients, setting clear standards for brain death determination and prohibiting commerce in this area. Since the Eurotransplant organization was founded, all member countries have installed donation- and organ transplant legislation. Gradually this has led to more governance, more accountability and more complexity of the cooperation system. In the following paragraphs the cornerstone principles of the various legislations are explained.

#### *1.4.1.1 Improving organ donation by becoming an organ donor*

Transplantation has become a successful routine procedure for people suffering from end-stage organ failure. The greatest limitation to its further success is the lack of suitable donors.
As transplantation has developed it has been important that the procedures for organ donation and transplantation have been regulated. In most western countries there is a formal legal framework in place. An adequate definition of brain death, a position regarding consent to organ donation as well as mechanisms to avoid the commercialization of organ transplantation should be included in this framework.

#### *1.4.1.2 Systems of organ donation*

Currently, two legal systems of organ donation are applied in Eurotransplant:

- *Presumed consent:* organ donation is automatically considered in patients diagnosed brain dead, unless they have specifically registered their wish not willing to donate. However, in some countries with a presumed consent law, doctors will still ask permission from relatives.
- *Informed consent:* organ donation is a voluntary act where relatives are asked to give permission at the time of brain death, usually in the knowledge that the potential donor had expressed a wish to be a donor.

Legal frameworks for organ donation in Eurotransplant:

| | **Legislation regarding organ donation** | |
|---|---|---|
| **Country** | **Presumed consent** | **Informed consent** |
| Austria | ✓ | |
| Belgium | ✓ | |
| Germany | | ✓ |
| Luxemburg | ✓ | |
| The Netherlands | | ✓ |
| Slovenia | ✓ | |
| Croatia | ✓ | |

#### 1.4.1.2.1 Austria

In Austria every person is a potential organ donor. People who object to organ donation, must register their data in the Widerspruchsregister, a databank of the Österreichisches Bundesinstitut für Gesundheitswesen (the Austrian health authorities). In practice, the next of kins opinions are also taken into account. Moreover, brain death is a condition for organ donation.
For more information, please contact:
Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG)
Stubenring 6
A-1010 Vienna
Austria
tel.: +43 1 5156170
fax: +43 1 5138472
Website: www.oebig.at

#### 1.4.1.2.2 Belgium

Belgium has had a law on organ donation since 1986. It states that every person, not objecting to organ donation during his lifetime, is automatically a potential donor. Immediately on its introduction, there was a substantial increase in the number of donors. In the past few years, however, the number of donors has stabilized. Also in Belgium the next of kins opinions are taken into consideration.
For more information, please contact:
Belgian Transplant Society (BTS):
Secretariat
Tel.: +32 3 821 3421
Fax: +32 3 829 0100
Website: www.transplant.be
E-mail: info@transplant.be

#### 1.4.1.2.3 Luxembourg

Luxemburg supports the presumed consent principle on organ donation. Since there is no central registry, the family is asked if the donor has opposed against donation. Brain death is a condition for organ donation.
For more information, please contact:
Luxembourg-Transplant
Tel.: +352 4411 2022
Fax: +352 4413 24
or
Ministere de la Santé, Division de la Medecine Preventive et Sociale
Tel.: +352 478 5562
Fax: +352 46 79 67

#### 1.4.1.2.4 Germany

On June 25, 1997 the Deutscher Bundestag, the German federal parliament, approved a bill regulating organ transplants. Organs may be removed from a donor at

the moment of total brain death, which must be confirmed by two independent doctors. Furthermore, a previous informed consent is required from the donor through a standard donor card or through verbal or written consent in the hospital. In its absence, a relative or partner may give his or her consent, but may not oppose any known wishes of the donor. On the subject of live donors the law is very strict: only a patient's close relatives or spouse may donate kidneys or part of the liver. The sale of organs has been banned.
For more information, please contact:
Deutsche Stiftung Organtransplantation (DSO)
Emil von Behring-Passage
63263 Neu Isenburg
Germany
Tel.: +49 6102 3008 0
Fax: +49 6102 3008 188
General information, tel.: 0800 90 40 400
Website: www.dso.de
E-mail: presse@dso.de

#### 1.4.1.2.5 The Netherlands

In 1996 the Dutch parliament ratified a law concerning organ donation which was implemented as of September 1, 1998. This included a national Donor Registry. A donor form has been sent to all residents over the age of 18 in which the following can be indicated: a yes or no decision, or the option of empowering the next of kin or another person to make the decision. Information filed in the Donor Registry can be revoked at any time. Doctors are obliged to consult the Donor Registry in case a deceased person seems to be a suitable donor. Should anyone not have made any arrangements by means of his registration form, then that right is transferred to his next of kin. In addition to the Donor Registry, also the donor card remained a legal document.
For more information, please contact:
NIGZ-Donorvoorlichting:
P.O. Box 500
3440 AM Woerden
The Netherlands
Tel: +31 900 821 21 66
Website: www.donorvoorlichting.nl

#### 1.4.1.2.6 Slovenia

In the spring of 2000, a law on organ donation passed the Slovenian parliament. Every person is a potential organ donor. However, the opinion of the family is decisive.
For more information, please contact:
Slovenija-transplant
University Medical Center
Zalolka 7
PP2219 1000 Ljubljana
Slovenia
Tel +386 1 3006864
Fax: +386 1 3006866
Website: www.slovenija-transplant.si

#### 1.4.1.2.7 Croatia

In December 2004, the Act on explantation and transplantation of the parts of the human body for therapeutic purposes passed the Croatian parliament. Every person is a potential donor unless he had objected to it in writing during his life. However, the opinion of the family is decisive. The Ministry of Health and Social Welfare keeps a non-donor register.
For more information, please contact:
Ministry of Health and Social Welfare
Ksaver 200 A
Zagreb,
Croatia
Tel: +385 1 4607538
Fax: +385 1 4677105
Website: www.mzss.hr

### 1.4.2 Ethical considerations in organ transplantation

However, the continuous shortage of donor organs makes the management of scarce treatment an important issue. It is in fact the reason for existence of Eurotransplant
In general the framework for the retrieval, allocation and transplantation of human organs for therapeutic reasons should be governed by principles and regulations that assure an orderly, ethical and acceptable handling and distribution of these scarce resources. Shared professional medical guidelines and standards, as well as ethical and legal standards should underpin these practices.
More information concerning the ethical considerations and issues can be found in the Ethical charter for Eurotransplant International Foundation (https://members.eurotransplant.org/cms/mediaobject.php?file=ET-Ethical-Charter1.pdf)

### 1.4.3 Privacy regulation

The Eurotransplant Privacy Agreement (version 01.04.2004) determines which patient- and donor-related data is stored, how it is stored and for how long the data is stored.

The Privacy Agreement fulfils the respective national requirements in the ET member countries and is available upon request.

## 1.5 Addenda

### 1.5.1 Articles of Association (AoA)

*1.5.1.1 Article 1. Name. Corporate Seat. Duration*

1.1. The name of the foundation is: Stichting Eurotransplant International Foundation and it has its registered seat in Leiden.
1.2. The foundation shall continue to exist for an indefinite period of time.

*1.5.1.2 Article 2. Definitions*

| | |
|---|---|
| Assembly | the meeting of Delegates; |
| Board | the Board of Management of the foundation as provided in article 6; |
| Centre | an institution or establishment which is entitled to a Eurotransplant Centre Code and in which programs are established under recognition of the competent and relevant authorities performing transplantations of Kidney, Thoracic Organs, Liver, Intestine, Pancreas and any part of a specific organ and/or where a Tissue Typing Centre exists; |
| Centre Code | a computer code provided by the foundation to a Centre; |
| Committee | a specific committee, as defined in article 11, paragraph 1; |
| Delegates | the persons defined in article 5.1; |
| Board of Directors | members of the Board of Directors as defined in article 8, paragraph 1; |
| Ethics Committee | the ethics committee as defined in article 10, paragraph 14; |
| Eurotransplant Reference Laboratory (ETRL) | a laboratory performing the foundation's reference tasks; |
| Financial Committee | the financial committee as defined in article 10, paragraph 13; |
| Nationality | nationality of the Centres; |
| National Scientific Transplant Societies | the societies established in Germany, Belgium, Luxembourg, Austria, the Netherlands, Slovenia and Croatia which pursue the objectives of the interests of the transplantation institutions in that particular country; |
| Reference Date | the thirty-first day of March of any year; on this day it shall be established how many transplantations per Program a Centre has performed in the Year preceding to the Reference Date in question; |
| Program | any of the following transplantation areas: Kidney, Heart, Lungs, Liver, Intestine, Pancreas or any part of a specific organ and/or Tissue Typing, which have the approval of the competent and relevant authorities; |
| Section | meeting of the Delegates representing a particular Program, which meeting shall be held during a meeting of the Assembly; |
| Tissue Typing Centre | an institution or establishment which is entitled to a TT code which under recognition of the competent and relevant authorities performs tissue typings; |
| TT code | a computer code provided by the foundation to a Tissue Typing Centre; |

Year the first day of January up to and including the thirty-first day of December.

*1.5.1.3 Article 3. Objectives*

3.1. The objectives of the foundation are:

a) to achieve an optimal use of available donor organs and tissues;
b) to secure a transparant and objective selection system, based upon medical criteria;
c) to assess the importance of factors which have the greatest influence on waiting list mortality and transplant results;
d) to support donor procurement to increase the supply of donor organs and tissues;
e) to further improve the results of transplantation through scientific research and to publish and present these results;

as well as the promotion, support and coordination of organ donation and transplantation in the broadest sense of the term and participation in concerted action at an international level where organ donation and transplantation is involved in a clinical or scientific sense, including all that may be conducive thereto.

3.2. The foundation is a non-profit organisation and does not have the intention to make profit as defined in the "Wet op de vennootschapsbelasting 1969".

*1.5.1.4 Article 4. Capital*

The capital of the foundation consists of the amount set aside by the founders at the time when the foundation was incorporated, and furthermore of contributions, subsidies, as well as amounts which will be obtained through donations, testamentary dispositions or bequests and all other income accruing to it.

*1.5.1.5 Article 5. The Assembly*

5.1 Each Centre shall have the right to delegate one natural person in the Assembly for each Program in which it performed transplantations during a year. On each Reference Date, the number of persons delegated (the "Delegates") by a Centre in the Assembly shall be reviewed.
5.2 The Assembly shall meet at least once a Year in a place and at such date to be established at the meeting of the Assembly in the previous Year.
5.3 The Assembly shall adopt and amend by-laws in which the organisation of the Assembly shall be regulated. Any provision of by-laws which is contrary to the articles of association is null and void. The Assembly shall adopt special by-laws in which the guidelines for the Committees will be laid down.
5.4 The number of votes which the Delegates of each Centre may cast in the Assembly shall be determined in connection with the number of transplantations in a certain Program performed by that Centre during the preceding Year as provided hereinafter. For the purpose of this article 5, the term transplantation shall also include living donor transplants. The following number of transplantations in a certain Program shall entitle the Delegates of a Centre to cast the following number of votes:
a. with respect to the Kidneys:

- one vote may be cast if the number of transplantations is less than fifty;
- two votes may be cast if the number of transplantations is fifty or more;

b. with respect to the Thoracic Organs:
- one vote may be cast if the number of heart transplantations is less than twenty;
- two votes may be cast if the number of heart transplantations is twenty or more;
- one vote may be cast if the number of lung transplantations is less than twelve;
- two votes may be cast if the number of lung transplantations is twelve or more;

c. with respect to Livers:
- one vote may be cast if the number of transplantations is less than twenty-five;
- two votes may be cast if the number of transplantations is twenty-five or more;

d. with respect to Pancreas and Islets:
- one vote may be cast if the number of transplantations is less than twelve;
- two votes may be cast if the number of transplantations is twelve or more;

e. with respect to Tissue Typing:
- one vote may be cast irrespective the number of tissue typings.

5.5 Each Delegate of a Centre shall cast the number of votes allocated to that Program, or those Programs of the Centre he represents pursuant to paragraph 4 of article 5.

5.6 The Assembly appoints for three years one of its members as its chairman. The Assembly shall also appoint for three years a secretary, whether or not from among its members.

5.7 Unless explicitly provided differently in these articles of association the Assembly shall adopt its resolutions with an absolute majority of votes cast. The chairman shall decide on the method of voting and on the possibility of voting by acclamation, provided, however, that voting with respect to appointment and dismissal of persons shall take place by means of sealed, unsigned, ballots. In a tie vote, the proposal shall have been rejected.

5.8 The Board shall attend the meetings of the Assembly and shall provide in such meetings all information required by the Assembly.

5.9 The secretary or chairman of the Assembly shall send the agenda of a meeting of the Assembly to each Centre at least thirty days prior to such meeting. In a meeting of the Assembly only such subjects may be discussed as described on the agenda referred to in the first sentence of this paragraph, unless it is decided in the meeting to put a subject on the agenda during the meeting, provided that at such meeting at least fifty percent of the votes which could be cast pursuant to paragraph 4 of this article is present or represented and at least two thirds of the votes cast was in favour of the proposal to add this subject on the agenda during the meeting.

5.10 Minutes shall be kept of the business transacted at a meeting of the Assembly. Minutes shall be adopted.

5.11 Meetings of the Assembly may also be attended by other persons than the Delegates, provided however that only Delegates shall be entitled to vote at such a meeting.

*1.5.1.6 Article 6. Board of Management.*

6.1 The foundation is managed by a Board of Management (the "Board"). The Board will be constituted as follows:

a. with due observance of the provision of article 6, paragraph 3, ten members will be elected from the Assembly of which:
   (i) three members of different nationality shall be involved with Kidney transplantations;
   (ii) one member shall be involved with Pancreas transplantations or any other part of a specific organ;
   (iii) two members of different nationality shall be involved with Liver transplantations;
   (iv) three members of different nationality shall be involved with Thoracic Organ transplantations, of which at least one member shall be involved in Lung transplantations;
   (v) one member with another nationality than the head of the Eurotransplant Reference Laboratory shall be involved with Tissue Typing,
   provided that these persons are working in a Centre,
   hereinafter collectively referred to as: members A;

b. six members shall be a member of the respective Boards of Management of the National Scientific Transplant Societies; each National Scientific Transplant Society shall be authorised to appoint the member in question, after the Board's prior approval, hereinafter collectively referred to as: members B;

c. one member shall be the head of the Eurotransplant Reference Laboratory, hereinafter collectively referred to as: member C;

d. two members will be elected by the Board of which one member shall be a financial expert on organ transplantation and one member shall be a representative of society or an ethicist familiar with the field of organ transplantation, hereinafter collectively referred to as: members D.

6.2 The Board shall at all times be composed as such that no nationality shall be represented in the Board for more than nine seats (or ten in case of the existence of a Past-President.

6.3 a. The members A and D of the Board shall be appointed for three years, with due observance of the provisions set out below in this respect, and shall retire in accordance with a schedule to be drawn up by the Board. Retiring members A and D are immediately eligible for reappointment.

b. If and when the Board appoints a member A as the President, the term of office for this member of the Board shall be extended for three years automatically and without the Assembly's intervention.

c. If and when the Board appoints a member A as the President-Elect, the term of office for this member of the Board shall be extended for four years automatically and without the Assembly's intervention. The maximum number of consecutive years a member A may serve on the Board, without having been reappointed by the Assembly, totals ten.

d. in the event of a vacancy on the Board with respect to a member A, the Board shall notify the Centres thereof at least three months prior to the meeting of the Assembly at which the vacancy shall be filled, mentioning the kind of vacancy with due regard for the provision in article 6, paragraph 1 under a, and inviting the Centres to nominate a candidate. Until one month prior to the meeting of the Assembly referred to in the preceding sentence, each person qualifying for the position of member A as provided in paragraph 1 of article 6 may by a notice in writing delivered by registered mail, put himself up for

candidate mentioning his name, his date of birth and his present profession.
On the agenda for the meeting of the Assembly during which the vacancy for the member A shall be filled, a list of the names and information of the candidates referred to in the preceding sentence shall be attached. Only the candidates mentioned on this list are available for election as member A. The members A shall be elected, after the Board's prior approval, in a Section by the Delegates of the Programme in which the vacancy occurs, as provided in article 6, paragraph 1 under a.

e. With respect to the election, only the Delegates of the Program concerned shall vote on the proposal to appoint a person as referred to under article 6, paragraph 1 under a as a member A of the Board. Article 5, paragraph 5 shall apply mutatis mutandis on the number of votes a Delegate may cast in the Section with respect to the appointment of a member A.
A member A for a Program shall be elected by an absolute majority of the votes cast at the Section of the Delegates representing the Program for which the vacancy for a member A exists.
A Delegate representing a particular Program may have himself represented at a Section by a fellow Delegate also representing that Program.
If at a vote regarding the appointment of a member A no absolute majority is obtained in the first vote of such Section, a new free vote shall be held.
If no absolute majority is then obtained either, a re-vote shall take place between the two persons who in the second free vote:
   a. obtained the highest number and the highest number but one; or
   b. obtained an equal number of votes, while no votes were cast on any other persons.

   If in the second free vote more than two persons meet the criterion referred to in paragraph a, a re-vote shall take place in the Section between the persons who obtained the highest number but one, but an equal number of votes. If after the second free vote more than two - but not all - persons meet the criterion referred to in paragraph b, a vote shall be held between those persons.
   If an interim vote or a re-vote leads to an equality of the number of votes cast, then the election shall be determined by lottery, which shall be performed by the chairman of the meeting.

6.4 The members B and C will be appointed in the capacity as described in article 6, paragraph 1, and the position within the Board as member B or member C will end when this capacity ceases to apply. Without prejudice to - and with due observance of – the provisions of paragraphs 1 and 3 respectively of this article 6, such a member B or member C may be appointed, after the Board's prior approval, as member A by the Section or the Assembly as the case may be.

6.5 The Board serves the interests of the foundation in the broadest sense of the term. The Board is empowered to adopt by-laws with regard to subjects to be determined by the Board. Provisions in these by-laws conflicting with the Articles of Association are null and void.

6.6 The Board shall elect a President and a Vice-President from the members A. The Board shall elect a Secretary/Treasurer from its midst. Prior to the final year of the President's term commences, the Board shall appoint a

President-Elect from the members A, who will prepare for the function of President in that final year of the President's term. A member of the Board shall start a new term of three years following appointment as President. Upon resignation of the President, the President-Elect will become the new President. If the President, President-Elect or Vice-President should retire for any reason whatsoever, the Board shall immediately fill the vacancy by a member A. Until that time, the respective function shall be taken over by one of the remaining 'Presidents'. Upon resignation as a President, President-Elect or Vice-President, a person shall not be eligible for the position of President, President-Elect or Vice-President for a period of three years. The Board can adopt a resolution to the extent that contrary to the aforementioned the retiring President, President-Elect or Vice-President is immediately eligible for reappointment, provided that such a resolution is adopted unanimously in a meeting in which all Board members are present or represented.

6.7 The Board can appoint a President who has completed his term as Past-President. The Past-President will render advice to the President-Elect and the President. The appointment as Past-President will be for a period of three years. The Past-President is the third member D of the Board.

*1.5.1.7 Article 7. Resignation of a member of the Board.*

7.1 Without prejudice to the provisions of Article 298 of Book 2 of the Civil Code, a member of the Board ceases to be a member of the Board:
   a. on his death;
   b. through resignation, voluntary or by rotation;
   c. as a result of his bankruptcy becoming irrevocable or his losing free control of his estate in any way other than as a result of a suspension of payments granted to him;
   d. with respect to members A and members D through dismissal with a notice addressed to him, jointly signed by the (other) members of the Board;
   e. with respect to a member A in the event that such member A does no longer satisfy the requirements as provided in article 6, paragraph 1 under a;
   f. by reaching the age of seventy;
   g. with respect to members B and C in the event as described in article 6, paragraph 4.

7.2 When a member of the Board ceases to be a member of the Board as a consequence of paragraph 1 of this article, his successor shall be in office for the time unfulfilled by his predecessor.

*1.5.1.8 Article 8. Board of Directors.*

8.1 The day-to-day management within the foundation, such under supervision of the Board, is the responsibility of the Board of Directors (the "Board of Directors").

8.2 The Directors are appointed by the Board. The Board of Directors consists of a number of one or more directors to be determined by the Board.

8.3 The duties and the extent of the authority of the Board of Directors shall be determined by the Board by way of an instruction to the Board of Directors.

8.4 The Board of Directors shall deliberate with the President, the Vice-President and the Secretary/Treasurer of the Board at least four times a Year and furthermore whenever a Director or the President of the Board so wishes.

*1.5.1.9 Article 9. Resignation and suspension of a director.*

9.1 A director ceases to be a director:
a. on his death;
b. through voluntary resignation;
c. through his having been declared in a state of bankruptcy in an irrevocable finding of a court of law, his losing control of his estate in any way, other than as a result of a suspension of payments granted to him, and through being placed under legal restraint;
d. through dismissal as a result of a resolution of the Board, of which resolution the director in question has been notified in writing;
e. by reaching the age of sixty-five.

9.2 The Board is authorized to suspend a director, in compliance with statutory provisions on this matter.

*1.5.1.10 Article 10. Organization of the Board.*

10.1 Every member of the Board shall have the right to cast one vote at meetings of the Board.

10.2 No valid resolutions can be taken unless at least an absolute majority of members are present or represented. If, at a meeting in respect of which members of the Board have been timely invited, not at least an absolute majority of members are present or represented, a second meeting shall be called, at which meeting valid resolutions can be taken regardless of the number of members of the Board present or represented.
A member of the Board can be represented at a meeting by a fellow member of the Board authorized in writing.

10.3 Meetings of the Board shall be chaired by the President, who shall however be authorized to appoint another member as the chairman of the meeting.

10.4 Unless otherwise provided in these articles of association, resolutions of the Board are taken by an absolute majority of votes of the members of the Board present or represented at the meeting. In a tie vote, the proposal shall be deemed to be rejected. A meeting attended by all the members of the Board can take legally valid resolutions, but only unanimously, even if no notice has been given.

10.5 Meetings are held at least twice a year and additionally as often as required by three members of the Board.

10.6 Notice of the meeting shall be given in writing by the Secretary of the Board or by the member of the Board who has requested the holding of the meeting, to each of the members of the Board with a notice period of at least fifteen days; the items on the agenda shall be specified in the notice of meeting.

10.7 The Board may invite directors to attend the meetings of the Board. If so invited, the directors shall attend such meetings and provide all information requested by the Board.

10.8 The minutes of a meeting of the Board shall be adopted.

10.9 The Board may also take resolutions without holding a meeting, provided that all members express themselves in favour of the proposal in question

in writing, by e-mail, telegraph or telecopier. The documents evidencing such resolution shall be included in the minute book.

10.10 The Board may also meet by telephone provided that at least two thirds of the sitting Board members are present during such meeting and that each member of the Board can hear and be heard. The Secretary shall ensure that what is discussed will be recorded in writing and sent to all the members of the Board and kept with the minute book.

10.11 Providing the number of members of the Board is at least ten (or eleven in existence of a Past-President), the Board is deemed to be fully composed during the existence of one or more vacancies.

10.12 The approval and authorization of the Assembly shall be required for resolutions of the Board:

a. to amend the articles 5, 10.2, 10.12, 13 and 20 of the articles of association of the foundation;
b. to dissolve the foundation;
c. to have the foundation merge with another legal entity.

10.13 The Board shall institute a Financial Committee consisting of 5 members of different nationalities. The chairman of the Financial Committee shall be the member D of the Board, being the financial expert, and 4 members shall be appointed by the Board, such at the proposal of the respective National Scientific Transplant Societies. The Financial Committee shall advise the Board on any financial matter of the foundation.. The Board may dismiss the members of the Financial Committee.

10.14 The Board shall institute an Organ Procurement Committee.
The members of the committee shall be appointed as follows:

- the following committees will each appoint one representative:
  a. the Committee instituted for Kidneys;
  b. the Committee instituted for Thoracic Organs;
  c. the Committee instituted for Livers;
  d. the Committee instituted for Pancreas and Islets;
  e. the Committee instituted for Tissue Typing;
- the following National Transplant Societies will each appoint a representative (the transplant coordinator):
  a. Austria;
  b. Belgium;
  c. the Netherlands;
  d. Slovenia;
  e. Croatia.

The National Transplant Society of Germany may appoint two representatives;

- the Ethics Committee may appoint one representative;
- one member shall be appointed from and by the Board, who will be the chairman of the Organ Procurement Committee.

10.15 The Board shall institute an Ethics Committee consisting of 5 members of different nationalities. The chairman of the Ethics Committee shall be the member D of the Board being the ethics expert of or the representative of the society, and 4 members shall be appointed by the Board, such as the proposal of the respective National Scientific Transplant Societies.
The Ethics Committee shall advise the Board on any ethics matter involving the foundation. The Board may dismiss the members of the Ethics Committee.

10.16 The Board may institute working groups for any area involving the foundation as it may deem fit.

### *1.5.1.11 Article 11. The Committees.*

11.1 With due observance of the provisions mentioned hereinafter, the Board shall institute with respect to each Program a specific committee (the "Committee"). Each Committee shall at all times be composed as such that:
a. no nationality shall have the majority of seats in a Committee;
b. no Program shall have more than one representative in a Committee; and
c. a member of a specific Committee should actively work in that specific Program.
The appointment of the member who will be the chairman of a Committee does not affect the composition of such Committee.

11.2 The members of the Committees shall be appointed as follows:
(i) with respect to the Committee instituted for Kidneys the members are appointed by the National Scientific Transplant Societies of Austria, Belgium, Luxembourg, Germany, the Netherlands, Slovenia and Croatia, as well as one member by the Section Tissue Typing in the Assembly,
– one member shall be appointed from and by the Board, who will be the chairman of the Committee instituted for Kidneys;
(ii) with respect to the Committee instituted for Thoracic Organs the members are appointed by the National Scientific Transplant Societies of Austria, Belgium, Germany, the Netherlands, Slovenia and Croatia,
– one member shall be appointed from and by the Board, who will be the chairman of the Committee instituted for Thoracic Organs;
(iii) with respect to the Committee instituted for Livers the members are appointed by the National Scientific Transplant Societies of Austria, Belgium, Germany, the Netherlands, Slovenia and Croatia,
– one member shall be appointed from and by the Board, who will be the chairman of the Committee instituted for Livers;
(iv) with respect to the Committee instituted for Pancreas and Islets the members are appointed by the National Scientific Transplant Societies of Austria, Belgium, Germany, the Netherlands, Slovenia and Croatia, as well as one member by the Section Tissue Typing in the Assembly,
– one member shall be appointed from and by the Board, who will be the chairman of the Committee instituted for Pancreas and Islets;
(v) with respect to the Committee instituted for Tissue Typing the members are appointed by the National Scientific Transplant Societies of Austria, Belgium, Germany, the Netherlands, Slovenia, Luxembourg and Croatia,
– one member shall be appointed from and by the Board, who will be the chairman of the Committee instituted for Tissue Typing.
The Board decides, at its own discretion or at the request of a National Scientific Transplant Society, bearing in mind that the transplant numbers of a country should be in balance with the assigned number of members of a respective Committee, on the number of members that a National Scientific Transplant Society may appoint in the respective Committee. In the event of a vacancy in a committee, the chairman of that committee shall immediately notify the chairman of the Board about the vacancy. With respect to a vacancy for a member of a committee appointed by a National Scientific Transplant Society, the chairman of that committee shall immediately inform in writing the National Scientific Transplant Society that

appointed the resigning member initially to appoint a new member. The members of the Committees shall be appointed for a period of two years. The members of the Committees will retire in accordance with a schedule to be drawn up by the Committee in question. Retiring members are eligible for immediate reappointment.

11.3 The membership of a Committee shall be personal. A member of a Committee may have himself represented in writing at a meeting of the Program to which he is a member only by a fellow member of that Committee.
11.4 The chairman of each committee shall be the member of the Committee which is appointed from and by the Board for that Committee in that position. Each Committee shall elect its vice-chairman. Each Committee shall elect either from its midst or from outside the Committee a secretary. The secretary of a Committee shall be responsible for the minutes of each meeting of a Committee.
11.5 Every member of a Committee shall at all times keep the secretary of the Committee in which he participates informed about any changes in his address. The secretary of a Committee shall give notice for a meeting and shall send the agenda of a meeting of a Committee to the members of the Committee at least fifteen days prior to such meeting.
11.6 A Committee shall meet at least two times a year and furthermore as often as required by the chairman of a Committee or two members of a Committee.
11.7 Resolutions of a Committee shall be adopted with an absolute majority of votes cast. Each member of a Committee shall have the right to cast one vote. In a tie vote, the proposal shall be deemed to be rejected.
A meeting attended by all members of a Committee can take valid resolutions, but only unanimously, even if no notice has been given.
11.8 A Committee may also take resolutions without holding a meeting provided that all members express themselves in favour of the proposal in question in writing, by e-mail, telegraph or by telecopier. The documents evidencing such resolution shall be included in the minute book.

*1.5.1.12 Article 12. Resignation of a member of a Committee.*

A member of a Committee shall resign from such a Committee:
a. if he no longer works in the Program for which he was appointed in that Committee;
b. with respect to a member A of the Board, if he resigns as a member from the Board as provided in article 7;
c. on his death;
d. through resignation, voluntary or by rotation;
e. as a result of his bankruptcy becoming irrevocable, his losing free control of his estate in any way other than as a result of a suspension of payments granted to him;
f. through dismissal by the Assembly.

*1.5.1.13 Article 13. Duties of the Assembly.*

The duties of the Assembly are:
a. pursuant to article 6, paragraph 3, to meet in order to enable the appointment of ten members A of the Board as provided for in article 6, paragraph 1, under a;

b. to approve certain resolutions of the Board as provided for in article 10, paragraph 12;
c. to discuss the reports of the various Committees;
d. to evaluate and discuss any subjects concerning the foundation and its objectives, not being a management subject as may be determined by the Assembly from time to time.

*1.5.1.14 Article 14. Duties of the Board.*

14.1 Without prejudice to the other provisions of these articles of association, the Board is responsible for managing the foundation and supervising the day-to-day management.
14.2 The duties of the Board include the taking of resolutions to:
   a. determine the nature, extent and function of the work of the foundation;
   b. determine the budget of the foundation;
   c. adopt and approve the annual accounts of the foundation;
   d. granting the approval for the five-year policy plan drawn up by the Board of Directors;
   e. enter into, amend or terminate - other than within the framework of the normal business of the foundation - agreements on cooperation with other institutions performing work similar to that of the foundation;
   f. reach settlements or appearances in court, including arbitration and binding recommendation procedures;
   g. file for bankruptcy and suspension of payments;
   h. appoint a person as referred to in article 20, paragraph 3;
   i. take on long-term debts;
   j. grant approval for agreements to buy, dispose of or encumber registered property and the conclusion of agreements whereby the foundation undertakes to stand surety as main co-debtor, warrants performance by a third party or undertakes to provide security for a debt of a third party and to conclude financing and other agreements to promote the objectives of the foundation, including agreements with national health services and insurance companies;
   k. grant approval as referred to in article 21, paragraph 4;
   l. issue rules with regard to the implementation of the objectives of the foundation on the basis of scientific development in the field of organ transplantation.
14.3 Without prejudice to the provisions of article 14, the Board may delegate powers to the Board of Directors.
14.4 The Board can obtain assistance in the fulfillment of its duties and charge the assistance to the foundation.
   This assistance may consist of incidental advice, but may also be of a more permanent nature; in the latter case the Board is under an obligation to file the agreement in question in writing. This assistance may also be rendered, for the purposes of specific expertise, by one or more members of the Board.

*1.5.1.15 Article 15. Duties of the Committees.*

15.1. Each Committee shall prepare and advise as to the following subjects:
   a. the definition and implementation of new rules for organ procurement and sharing;

b. the monitoring of specific allocation procedures within the foundation, including the Centre Codes;
c. the formulation of short-comings in the allocation procedures;
d. the draw up of adaptations and the implementation schedules;
e. the examination of comments on the allocation procedures;
f. the review of non-compliance by a Centre with allocation procedures;
g. the proposal and suggestion of measures and/or sanctions in the event of non-compliance of a Centre of the allocation rules;
h. data collection and scientific analyses.

Furthermore, the Committee instituted for Tissue Typing shall prepare and advise as to the following subjects:

a. the introduction of new tissue typing and matching procedures;
b. the performance of the Tissue Typing Laboratories in relation to the standards of the foundation.

The Board may request advice from a Committee for any matter relating to the Program for which the Committee has been instituted.

15.2 A Committee shall document the advices referred to in paragraph 1 of article 15 in a report to the Assembly at least one time a year. In the event that a Committee advised the Board pursuant to a request as provided in paragraph 1 of this article 15 and with due observance of the guidelines as provided for in article 5, paragraph 3, such a Committee shall in a written report notify the chairman of the Assembly thereof. In the event that the guidelines as referred to in article 5, paragraph 3 require that a Committee may only render such an advice upon consultation with the Assembly, the Committee in question shall only give an preliminary advice to the Board.

15.3 Each Committee shall adopt by-laws in which the organization of a Committee shall be regulated. Any provision of by-laws which is contrary to the articles of association is null and void.

*1.5.1.16 Article 16. Duties of the Board of Directors.*

16.1 Execution of day-to-day management of the foundation is the responsibility of the Board of Directors.

16.2 The duties of the Board of Directors include in particular:

a. the preparation and execution of resolutions of the Board;
b. the day-to-day management of movable and immovable property of the foundation;
c. the day-to-day management of the financial funds;
d. the effective operation of the organization;
e. the maintenance of external contacts;
f. the care for the accommodation;
g. the preparation and drawing up of the budget, the annual accounts and the annual report;
h. the drawing up of a proposal for and implementation of an approved five-year policy plan;
i. the conducting of summary proceedings - both as claimant and as defendant - and in general the taking of legal actions which admit of no delay or are purely of a distraint nature;
j. in general all matters which may reasonably be considered to belong to the day-to-day management, or have been passed to the Board of Directors by the Board, as the case may be.

16.3 The Board may request the Board of Directors to provide additional information with respect to one or more of the subjects mentioned in

paragraph 2 of this article, incidental as well as on a continuing basis.

*1.5.1.17 Article 17. Representation.*

17.1 The foundation shall be represented in court and otherwise by the Board or two members of the Board, acting jointly.
17.2 The Board can give a director continuing or non-continuing proxy.

*1.5.1.18 Article 18. Financial year, annual accounts and financial management.*

18.1. The financial year shall be the calendar year.
18.2. The Board is under an obligation to keep such records of the financial position of the foundation that its rights and obligations may be known at any time. Annual accounts for the past year are prepared and adopted by the Board before the first of July following the end of the financial year. The Board is under an obligation to retain these documents for ten years. The annual accounts shall be signed by the President and Secretary/Treasurer of the Board and accompanied by a report on the activities and conduct of business in the financial year in question. The provisions of Part 9, Book 2 of the Civil Code shall be applicable to the annual accounts and annual report. After approval by the President the annual accounts and the annual report will be published.
18.3. The Board appoints a member of the Netherlands Institute of Chartered Accountants (Nederlands Instituut van Registeraccountants) to audit the annual accounts.

*1.5.1.19 Article 19*

19.1 Except as prescribed in paragraph 4 of this article, only the annual proceeds of the capital of the foundation may be used for the objectives of the foundation, plus the income received in any year, under whatever name, which is not intended to be set aside as capital.
19.2 If in any year the funds available for the accomplishment of the objectives of the foundation are only partly used, the Board determines whether or to what extent the balance not used is added to the capital or is reserved for future accomplishment of the objectives.
19.3 The Board is free to invest and re-invest the capital of the foundation.
19.4 The Board may only use the capital of the foundation for the accomplishment of the objectives of the foundation.

*1.5.1.20 Article 20. Amendment of AoA; dissolution.*

20.1 The Board is entitled to make amendments to these articles of association with due observance of these articles of association; a resolution to do so may only be taken by a majority of at least two-thirds of the votes. An amendment to the articles of association comes into effect by notarial instrument.
20.2 If the Board is of the opinion that the objects of the foundation cannot or can no longer be accomplished, it can dissolve the foundation with due observance of these articles of association; a resolution to dissolve is likewise taken by a majority of at least two-thirds of the votes.
20.3 In the event of dissolution, the foundation will be wound up by the members of the Board acting at that time; the articles of association continue to apply

accordingly to the winding up of the foundation, and also to the filling of vacancies.

20.4 After all debts have been paid in full, the balance of the assets remaining shall be allocated, as far as possible within the meaning of article 2, paragraph 1, in a manner to be determined by the Board.

*1.5.1.21 Article 21*

All cases falling within the limits of these articles of association but not regulated in them shall be provided for by a resolution of the Board.

### 1.5.2 Eurotransplant Advisory Committee

*1.5.2.1 Institution of Committees*

According to the Articles of Association (see 1.5.1), the ET Board shall institute Committees (see 1.5.1.10 (10.13, 10.14, 10.15, 10.16), 1.5.1.11 and 1.5.1.15). Every Committee is chaired by a Board member.

*1.5.2.2 Committees in Eurotransplant*

4 organ-specific Advisory Committees are in effect:

- Kidney Advisory Committee (ETKAC)
- Thoracic Advisory Committee (EThAC)
- Liver Intestine Advisory Committee (ELIAC)
- Pancreas / Islets Advisory Committee (EPAC)

Other existing Advisory Committees:

- Tissue Typing Advisory Committee (TTAC)
- Financial Committee (FC)
- Ethics Committee (EC)
- Organ Procurement Committee (OPC)
- Information Services Working Group (ISWG)

### *1.5.2.3 Structure of Advisory Committees*

#### 1.5.2.3.1 Number of participants

The Committees are composed of representatives of each of the Eurotransplant countries. Currently, the number per Advisory Committee is as follows:

| **Country / Committee** | **Kidney** | **Thoracic** | **Liver** | **Pancreas** | **Tissue Typing** | **FC** | **EC** | **OPC** | **ISWG** |
|---|---|---|---|---|---|---|---|---|---|
| Austria | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Belgium | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Croatia | 1 | 1 | 1 | 1 | 1 | - | - | - | - |
| Germany | 4 | 4 | 3 | 3 | 2 | 1 | 1 | 2 | 1 |
| Luxembourg | 1 | - | - | - | 1 | - | - | 1 | - |
| Slovenia | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| The Netherlands | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Tissue Typing | 1 | - | - | 1 | - | - | - | 1 | 1 |
| Representative from the Board | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Total** | **15** | **13** | **10** | **10** | **9** | **5** | **6** | **8** | **7** |

However, according to article 1.5.1.11 (11.2) of the AoA, the Board decides, at its own discretion or at the request of a National Transplant Society, the number of members of a respective National Transplant Society allowed to be appointed for an organ-specific Advisory Committee. For this purpose, it will be taken into account that a country's number of transplants is in balance with the assigned member of a respective Committee appointed by that country's e National Transplant Society.

The OPC has 11 members:
- one representative from the 4 ET organ-specific Advisory Committees;
- one representative from each of the 5 national transplant society (2 for Germany);
- one representative from the Ethics Committee;
- one Board member.

The ISWG has 10 members:
- one representative from the 4 ET organ-specific Advisory Committees;
- one representative from each of the 5 national transplant society (2 for Germany);
- one representative from the TTAC;
- one Board member.

#### 1.5.2.3.2 Appointment of participants

- Committee members are appointed by the national transplant societies (apart from OPC and ISWG, see above);
- each member should be appointed for a period of two years, with possibility for

re-appointment;
- when a member ceases to be a member of a Committee, his successor shall be in office for the time unfulfilled by his predecessor;
- the chairperson is a member from and appointed by the Board;
- there should not be more than one representative per center;
- a member may have himself be represented only by a fellow member of that Committee;
- members of an organ-specific Advisory Committee should be active in that specific field of organ transplantation.

1.5.2.3.3 Organization of the Committee

- the Committee elects from its midst a vice-chairperson;
- the Committee shall elect, either from its midst or from outside the Committee, a secretary;
- each member has the right to cast one vote;
- resolutions of the Committee are taken by absolute majority of votes of participants present at the meeting;
- the secretary makes minutes within one month after the meeting; these minutes must be approved by the chairman on behalf of the Committee;
- each Committee can decide to appoint external advisors; these advisors have no voting power.

*1.5.2.4 Status of the Committees*

The Committees are advisory to the Board. The ET Board should approve the recommendations and:
- check if the proposed rules are suitable for implementation (financially and practically);
- be responsible to monitor if the proposed rules of the various Committees are geared for one another;
- take care that the approved recommendations are implemented properly and according to time schedule;
- provide the organ-specific Advisory Committees with administrative support.

The ET Board can delegate the above described responsibilities to the Board of Directors.

*1.5.2.5 Publication of recommendations approved by the Board*

The recommendations of organ specific Advisory Committees are published in the ET Newsletter after approval by the Board. ET users are encouraged to react on these publications.

*1.5.2.6 Meeting schedule*

A Committee meets at least twice a year or more, if required by the chairperson or two of its members. By-laws have been written for each Committee and will be provided for at an individual's request (see 1.5.1.15 (15.3)).

### 1.5.3 Policy statement Eurotransplant Computer System

#### *1.5.3.1 Introduction*

Since the Eurotransplant Computer System (ECS) contains decentralized generated data which is centrally administrated, it is necessary to define responsibilities, policies, procedures with respect to ownership, accuracy and changes within this data base structure.

#### *1.5.3.2 Policy Statement*

##### 1.5.3.2.1 Ownership of the data

The local centers within Eurotransplant are the originators of the data and the owners of their own data. The Eurotransplant organization has been entrusted by the local centers with the custodianship and administration of the centrally stored information. This administrative task is not a new function generated by the ECS but rather a continuation of the Eurotransplant activities.

##### 1.5.3.2.2 Data base contents

Since the local centers are the originators of their data, they are responsible for the accuracy of their own data. The responsibility for the accuracy of data is not restricted to the locally generated data but also to the data entrusted to Eurotransplant for central administration within the ECS. Eurotransplant will take responsibility for designing and maintaining procedures for the safe keeping and stability of the data entrusted to Eurotransplant's custodianship. For that purpose, Eurotransplant will provide facilities that allow the local centers to verify the consistency of the locally generated data with the centrally stored data. It still remains the responsibility of the local centers to resolve possible inconsistencies between the locally and centrally generated data with the assistance of ET.

##### 1.5.3.2.3 Changes to data

Changes to the data will only be made by the owner of the data, the local centre. Upon request of the local center, Eurotransplant will undertake the desired changes. The center is responsible for the data changes regardless of who performs these changes.

##### 1.5.3.2.4 Definition and functionality of the ECS

The implementation of changes and of additions to the data base definition and system functionality which are approved by the Information Services Working Group (ISWG) are the responsibilities of the Eurotransplant management in Leiden in conjunction with the centers.

#### *1.5.3.3 Procedures for the implementation of the policy statement*

##### 1.5.3.3.1 Procedures regarding ownership of data

The procedures for the acquisition of the data are the responsibility of the local

centers. All necessary and sufficient administrative procedures, included but not limited to those legally required, are to be performed by the local centers. All data entrusted to the central storage facilities of the ECS in Leiden, must meet these requirements.

1.5.3.3.2 Procedures regarding accuracy of data

Centrally stored data will be made available to the local centers for the purpose of data consistency checks. These data will be made available, upon request, from the ET office to the local centers via either the standard ECS computer link or printed lists. Resolution of data inconsistency will be performed by the local centers via the centers processing facilities, where possible assisted by ET. All efforts will be made by ET that an optimal data protection is available.

1.5.3.3.3 Procedures regarding data changes

Procedures for entering and changing data in the ECS are described in the appropriate user manual available at the member site (www.eurotransplant.org).

1.5.3.3.4 Procedures regarding changes of definition and functionality of ECS

Changes and additions to the definition and functionality of the ECS affecting the quality and nature of the services to the local centers, require approval of the Information Services Working Group (ISWG). The procedures will be performed only at the ET office in Leiden.