Eurotransplant Manual

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The Eurotransplant Manual contains the rules and regulations for the implementation and specification of national legislation and national guidelines for waiting list management, organ procurement and allocation. It has been prepared with the best of knowledge and the utmost care. In case of discrepancies between the content of this manual and national binding provisions, the following applies:

- Insofar, as provisions about the acceptance of organ recipients to the waiting list are concerned, this manual has only an informative character. Only the national provisions which are applicable for the transplant centers are relevant and legally binding.
- For the allocation of organs only the national provisions are legally binding. The display of the allocation provisions in this Manual are based on these legally binding national provisions. As far as necessary, they have been specified by Eurotransplant in this Manual. Deviations from such specifying Eurotransplant provisions cannot be considered as a breach of the national provisions as long as the latter are not violated. Eurotransplant cannot be held liable for a potentially wrongful description in this Manual of procedures, in connection with the organ allocation, as long as the actual allocation follows national provisions.

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1.1 Introduction

Eurotransplant International Foundation (ET) operates based on the following principles (TORA-V)¹:
- Transparency,
- Objectivity
- Reliability
- Accountability
- Validity

Transparency, objectivity, reliability and accountability are maintained and enforced in and by the ET office. The validity of the work that is done at the ET office is developed by the organ Advisory Committees based on the most recent scientific developments in the organ transplantation field.

These principles are reflected in the ET Manual.

ET aims at harmonization between all member states on all aspects from donor characterization to follow-up. For all member states there is a basic minimum that needs to be adhered to. These minimal requirements are specified in the ET Manual.

The ET Manual is accessible to the general public on the public website; however the main target group is the professionals in the transplant field. If a non-transplant professional has questions about the ET Manual or cannot interpret it correctly a transplant professional should be consulted.

The ET Manual contains the following information:
- Definitions used in the ET area;
- Additional background information regarding rules and regulations in the ET area;
- Reference to guidelines and procedures of ET: based on the minimal guidelines specified by the OPC;
- The consensus on international exchange policies;
- Organ specific waiting list rules (regarding listing for high urgency criteria for international exchange);
- The methods of work in the donor and recipient hospitals.

¹ © Implemented by Dr. A. Rahmel in 2010
1.2 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. Dr. 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. 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.

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.

In July 2006, the Republic of Croatia began its candidate membership, resulting in a permanent membership in May 2007. Hungary joined Eurotransplant in July 2013 as full member, after a candidate membership since January 2012.

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 eight European countries with over 135 million inhabitants.
1.3 The Eurotransplant concept

Eurotransplant (ET) is an international, non-profit organ exchange organization who is responsible for the allocation and international exchange of post-mortem donor organs. ET coordinates donation procedures across a region with over 135 million inhabitants, providing services to transplant centers, tissue typing laboratories and donor hospitals in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia.

1.3.1 Mission statement and goals

1.3.1.1 Mission statement

Organ transplantation offers life-saving and quality-of-life enhancing treatment options to patients with end-stage organ failure. Aiming to fulfill this potential, Eurotransplant was established and acts as a mediator between donor hospitals and transplant centers, for the benefit of such patients.

Eurotransplant is a non-profit international service organization that facilitates patient-oriented allocation and cross-border exchange of deceased donor organs at the service of its member states. As such,

• Eurotransplant manages the complex process of achieving the best possible match between available donor organs and patients on the transplant waiting list
• Eurotransplant acts transparently and in accordance with European Union regulations and ethical principles, and fully complies with national member states legislation
• Eurotransplant is actively engaged in developing best practice recommendations and policies to further improve organ allocation and transplant outcomes, based on robust data collection and state-of-the-art scientific research.

1.3.1.2 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.

1.3.1.3 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, the patient 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.
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:

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<td>Heart + Lung</td>
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<td>Liver</td>
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<td>Intestine</td>
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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.

1.3.1.4 Science

After the recipient has undergone the 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 selection of the most suitable recipients. 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.

1.3.2 Organizational structure

ET is operated by the central office in Leiden, the Netherlands, and is composed of the Assembly, the Board, the Board of Directors and the Advisory Committees (see Addenda 1.6.1, Articles of Association).

1.3.2.1 Program director and delegate of a transplant center

Program director

The program director head of a transplant program appointed by the medical director of a Centre/hospital.
Delegate

The head of the transplant center can appoint the delegate of the transplant center for the ET Assembly.

The Head of an ET organ transplant program and the Delegate are the main contact persons for ET for all formal requests related to that transplantation program. They are responsible for granting access to ENIS for all members of this transplant program.

Each Program Director shall have the right to delegate up to two natural persons in the Assembly for each Program in which transplantations were performed during the preceding Year.

1.3.2.2 The Assembly

All individual transplant centers are represented in the Assembly. Each transplant program may delegate one or two representative(s), depending on the number of transplants performed in the preceding year.

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.

1.3.2.3 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);
- 7 members are elected in virtue of their organization (chairmen of the 7 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.

For details see Addenda, Articles of Association (1.6.1).

1.3.2.4 Board of Directors

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").

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.

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.

**Duties of the Board of Directors.**

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

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 organisation;
e. the maintenance of external contacts;
f. the care for the accommodation;
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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.

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.

1.3.2.5 Advisory Committees

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. 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 the Board 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 (1.6.1).
1.3.2.6  Organizational chart - Eurotransplant

ET Transplant programs

Assembly

ET Reference Laboratory (ETRL)
- 1 representative (head of dept)
  10 representatives
  1 representative

Ethics expert

Financial expert

Past President

National Transplant Societies:
  Austria, Belgium, Luxembourg,
  Germany, The Netherlands,
  Slovenia, Croatia, Hungary

Board

chairperson

ETKAC  TTAC
ThAC  OPC
ELIAC  FC
PAC  EC
ISWG

Each 1 delegate

represents
1.3.3 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.

1.3.3.1 Organizational chart – ET central office

1.3.4 Eurotransplant Manual

The Eurotransplant Manual, as published and accessible through the website at www.eurotransplant.org contains the official rules and regulations of Eurotransplant. These regulations must be followed by all ET users.

These rules or regulations are defined as “recommendation” or “policy”. Following are the two definitions which describe the role of national authorities that are formally responsible for allocation guidelines.

1.3.4.1 Eurotransplant Recommendation

Recommendations that formally fall under the competence of the responsible national authorities in some countries. These recommendations have to be approved by the responsible national authorities of these countries prior to implementation. A typical example of a Eurotransplant recommendation according to this distinction would be a change in allocation rules.

\[^3\] RET01.05 accepted by the ET Board on January 19, 2005.
With the approval of the recommendation by the responsible national authority it becomes binding in that country and ET can refer to this approval and use the respective national authority to enforce the recommendation.

1.3.4.2 Eurotransplant Policy

Recommendations that concern a working procedure or policy of Eurotransplant. These recommendations are only sent for information to the national authorities; their main goal is to increase transparency of the working procedures of ET and its partners. An example of a Eurotransplant policy according to this distinction is the Board recommendation regarding the development of new recommendations which is described on the next pages.

1.3.5 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 users³.

1.3.6 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.

1.3.7 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

³ RET01.05 accepted by the ET Board on January 19, 2005.
signed by the Health Ministers of the eight ET member countries (see 1.4).

The policy statement Eurotransplant computer system (see Addenda, 1.6.3) 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
- Hungary
  - Hungarian National Blood Transfusion Service

### 1.3.7.1 Candidate membership

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

More information about these prerequisites can be found on the Eurotransplant website [www.eurotransplant.org](http://www.eurotransplant.org).

### 1.3.8 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.

### 1.3.9 Collaboration between programs/centers

An intended cooperation 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, its consequences and evaluate if this cooperation is in accordance with existing allocation rules and/or Articles of Association.
1.4 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 of 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,
The Minister of Health and Social Welfare of Croatia, and
The Ministry of Health of the Republic of Hungary,

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

1.4.1 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.

1.4.2 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.
1.4.3 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\(^4\). 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.

\(^4\) 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.
1.4.4 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,
  o Magda Aelvoet
- Bonn, The Federal Minister of Health of the Federal Republic of Germany,
  o Andrea Fischer
- Luxembourg, The Minister of Health of the Grand Duchy of Luxembourg,
  o Georges Wohlfahrt
- The Hague, The Minister of Health, Welfare and Sport of the Kingdom of the Netherlands,
  o Els Borst-Eilers
- Vienna, The Federal Minister of Labour, Health and Social Affairs of the Republic of Austria,
  o Lore Hostasch
- Ljubljana, The Minister of Health of the Republic of Slovenia,
  o 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

The Minister of Health of the Republic of Slovenia,

and

The Ministry of Health of the Republic of Hungary,

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*
Chapter 1 – Introduction

1.5 Legal and ethical considerations in Eurotransplant

1.5.1 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.

1.5.1.1 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.

1.5.1.2 Systems of organ donation

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

- Presumed consent or opting out: organ donation is automatically considered in patients diagnosed brain dead or potential donor after circulatory death, 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, decisive consent or opting in: organ donation is a voluntary act where the donor must have expressed a positive view of organ donation if organs are to be removed from the dead body. In case no expression on organ donation has been made by the donor the relatives are asked to give permission at the time of brain death / potential donor after circulatory death

Legal frameworks for organ donation in Eurotransplant:

<table>
<thead>
<tr>
<th>Country</th>
<th>Legislation regarding organ donation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Presumed consent</td>
</tr>
<tr>
<td>Austria</td>
<td>✓</td>
</tr>
<tr>
<td>Belgium</td>
<td>✓</td>
</tr>
<tr>
<td>Germany</td>
<td>✓</td>
</tr>
<tr>
<td>Luxemburg</td>
<td>✓</td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>✓</td>
</tr>
<tr>
<td>Croatia</td>
<td>✓</td>
</tr>
<tr>
<td>Hungary</td>
<td>✓</td>
</tr>
</tbody>
</table>
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)
Website: www.oebig.at

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):
Website: www.transplant.be
E-mail: info@transplant.be

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

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, part of the liver or part of lungs. The sale of organs has been banned.

For more information, please contact:
Deutsche Stiftung Organtransplantation (DSO)
Website: www.dso.de
E-mail: presse@dso.de

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:
Website: www.donorvoorlichting.nl

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
Website: www.slovenija-transplant.si

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 the donor 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
Website: www.mzss.hr

Hungary

The ACT No. CLIV OF 1997 ON HEALTH, Chapter XI regulates organ donation in Hungary, since 1997. Hard type of presumed consent system is described and further detailed in the 18/1998. (XII. 27.) Ministerial Decree. Every adult person is a potential donor unless he had objected to it in writing during his life. However, the family refusal may be accepted and so donation cancelled by the donor hospital. Organ procurement from pediatric brain death patient is only allowed after having written permission of the parents. The National Public Health and Medical Officer Service, National Institute of Chemical Safety keeps a non-donor register (National Transplantation Registry).

For more information, please contact:
Organ Coordination Office, Hungarian National Blood Transfusion Service
Website: www.hnbts.hu/oco
E-mail: coordinator@ovsz.hu

1.5.2 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 http://www.eurotransplant.org/cms/mediaobject.php?file=ET-Ethical-Charter.pdf
1.5.3 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 fulfills the respective national requirements in the ET member countries and is available upon request.
1.6 Addenda

1.6.1 Articles of Association (AoA)

The Articles of Association are displayed on the Eurotransplant Website.

1.6.2 Eurotransplant Advisory Committee

1.6.2.1 Institution of Committees

According to the Articles of Association (see 1.6.1), the ET Board shall institute Committees and every Committee is chaired by a Board member.

1.6.2.2 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 (ITAC)
- Financial Committee (FC)
- Ethics Committee (EC)
- Organ Procurement Committee (OPC)
- Information Services Working Group (ISWG)
1.6.2.3 Structure of Advisory Committees

Number of participants

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

<table>
<thead>
<tr>
<th>Country / Committee</th>
<th>Kidney</th>
<th>Thoracic</th>
<th>Liver</th>
<th>Pancreas</th>
<th>Tissue Typing</th>
<th>FC</th>
<th>EC</th>
<th>OPC</th>
<th>ISWG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
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<td>Belgium</td>
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<td>Croatia</td>
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</tr>
<tr>
<td>Germany</td>
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<tr>
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<tr>
<td>Luxembourg</td>
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<tr>
<td>The Netherlands</td>
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<tr>
<td>Slovenia</td>
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<tr>
<td>Tissue Typing</td>
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<tr>
<td>Representative from the Board</td>
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<tr>
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<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
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<td>14</td>
<td>9</td>
<td>11</td>
<td>10</td>
<td>6</td>
<td>8</td>
<td>14*</td>
<td>14*</td>
</tr>
</tbody>
</table>

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 National Transplant Society. For more information see Articles of Association (see 1.6.1).

The OPC has 14 members:
- one representative from the 4 ET organ-specific Advisory Committees;
- one representative from each of the 7 national transplant society (2 for Germany);
- one representative from the Tissue Typing Committee;
- the possibility to appoint one representative from the Ethics Committee;
- one Board member.

The ISWG has 14 members:
- one representative from the 4 ET organ-specific Advisory Committees;
- one representative from each of the 7 national transplant society (2 for Germany);
- one representative from the TTAC;
- one Board member.

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.

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.

1.6.2.4 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.

1.6.2.5 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.

1.6.2.6 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)).

1.6.3 Policy statement Eurotransplant Computer System

1.6.3.1 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.

1.6.3.2 Policy Statement

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 contractually entrusted by the local centers with the custodianship, processing 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.

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.

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.

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.

1.6.3.3 Procedures for the implementation of the policy statement

Procedures regarding ownership of data

The procedures for the collection 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.

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.
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).

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.