Chapter 2

The Recipient
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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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2.2.3 Registration of a transplantation
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2.3 FORMS
2.1 Post-mortem organ transplantation

2.1.1 Mandatory prospective listing

Patients are listed prospectively, i.e. prior to the transplantation, on an ET waiting list awaiting a single or multi-organ post-mortem donor (re)transplant. Patients listed for a post-mortem organ transplant are not excluded from transplantation with an organ from a living donor.

ET does not apply official listing criteria. The specialist in charge of the transplant program has the responsibility that the patient's indication for a post-mortem organ transplantation is in accordance with current national guidelines.

The decision to register a patient on the waiting list for a combined transplantation should be taken in consultation by the transplant specialists of all organs involved.

2.1.1.1 Deviant national agreements

2.1.1.1.1 Germany

All patients awaiting either a post-mortem or a living donor organ transplantation must be registered prospectively on an ET waiting list.

2.1.1.2 Organ specific requirements

2.1.1.2.1 Pancreas

A patient on the pancreas waiting list must be diagnosed with Diabetes mellitus type I or a pancreas deficiency. Doubtful cases can be submitted to ET for evaluation by the ET Pancreas Advisory Committee (EPAC).

2.1.2 Registration procedure

The following items in the registration procedure are mandatory to assign a patient his/her unique ET number:

- date of registration;
- registering transplant center;
- last and first name (in married women also the maiden name);
- date of birth;
- gender;
- address, postcode and city;
- country of residency;
- nationality
- BSN (only for the Netherlands)
- insurance company and number (Germany and Netherlands only);
- physician's declaration that the patient was informed and explicitly agreed about:

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1 P-ET 01.16 approved September 28, 2016
2 Richtlinien zur Organtransplantation gemäß §16 TPG, published by the Bundesärztekammer (www.baek.de).
Chapter 2 – The Recipient

- Eurotransplant,
- policies on waiting list management and organ allocation,
- the fact that administrative and medical data are forwarded to ET before and after a transplantation.

For further information, please refer to the ENIS manual (Chapter 3) in the Library of the member’s area at www.eurotransplant.org.

Due to the General Data Protection Regulation (GDPR), which has come into effect on May 25, 2018, a patient/living donor has to give explicit consent, that his or her data may be used by Eurotransplant, exchanged with national or international registries and used for scientific research related to allocation development.

Therefore the registering physician has to state in the registration if the patient agrees or disagrees in writing to the above mentioned. For the registration of a living donor and/or the patient the physician has to fill in his/her name. In case no decision has been made by the patient or if a physician is unaware of the actual consent, the consent field will have to be filled in with “Unknown”.

All consent registrations can be changed at any time, and depending on the consent ET is allowed to exchange or use data for scientific research.

Please be aware that a patient has to consent to the use of data necessary for allocation.

The following fields are available in the consent authorization:

- National registries (yes/no/unknown)
- International registry ISHLT (yes/no/unknown)
- International registry CTS (yes/no/unknown)
- International registry CERTAIN (yes/no/unknown)
- International registry ELTR (yes/no/unknown)
- Scientific research (yes/no/unknown)

In the Netherlands there are two national registries (NOTR and Renine) and one field for consent of a relative donor.

Before completing the registration procedure, the user must confirm that the patient was informed on all aspects according to national legislation and common standards.

The patient’s data in ENIS must, at all times, correspond with his/her current clinical status.

2.1.2.1 Registration outside office hours

Outside office hours, non-renal patients will only be registered by the ET duty desk if a patient is granted the high urgent status (HU). All other patients must be registered by the individual transplant center.

2.1.3 Waiting list management

2.1.3.1 Waiting list urgency code

To have the patient placed on an ET waiting list after the initial registration procedure, one or more organs must be selected together with an active urgency, i.e. any urgency other than ‘temporarily not-transplantable’ (NT). Only in an active urgency will a patient be selected in a
match procedure from a suitable post-mortem donor. Patients in NT are not selected. For further information, please refer to the ENIS manual at www.eurotransplant.org.

Urgency codes can vary between organs. Please refer to the organ-specific chapters elsewhere in this manual.
Heart and/or lung ET Manual CH06
Liver ET Manual CH05
Kidney ET Manual CH04
Pancreas ET Manual CH07

2.1.3.1.1 High Urgent (HU)/Special Urgency (SU)

A HU/SU status for a transplant candidate must be requested by the transplant center through the corresponding organ-specific form. The form has to be completed on all items and then be sent to the ET duty desk. The form is either evaluated by the ET medical staff, members from organ-specific advisory committee or an (inter)national audit group. Only upon approval by either of these will the higher allocation priority be granted and changed in ENIS by the ET duty desk.

All forms are available in section Forms of the Library of the member’s area at www.eurotransplant.org.

2.1.3.2 Listing for a multi-organ transplantation

A patient can be listed on the waiting list for more than one organ. If a patient is already listed for one organ, only the waiting list procedure for the other organ(s) is required. It is not necessary to repeat the initial registration procedure. For further information, please refer to the ENIS manual at www.eurotransplant.org.

2.1.3.2.1 Approved Combined Organ (ACO)

A higher allocation priority, below HU and prior to elective (T), can be requested for multi-organ transplantations including at least two different non-renal organs, for heart-lung transplantation no ACO status can be requested, for this combination special allocation rules apply (s. chapter 06).

For further information, please refer to the organ-specific chapters elsewhere in this manual.
Heart and/or lung ET Manual CH06
Liver ET Manual CH05
Kidney ET Manual CH04
Pancreas ET Manual CH07

2.1.3.3 ENIS donor profile

2.1.3.3.1 Center-specific donor profile

A transplant center can indicate a center-specific profile that is automatically applied to all the center’s patients registered on an ET waiting list at the time of a match selection from a donor.

For further information, please refer to the ENIS manual (chapter 7 in the Library of the member’s area at www.eurotransplant.org).
2.1.3.3.2 Recipient-specific donor profile

A transplant center can, in addition to the center-specific profile, enter a recipient-specific donor profile that is applicable only for this particular patient. In case a recipient-specific donor profile is present at the time of a match selection, then this profile has priority over the center-specific profile.

For further information, please refer to the ENIS manual (chapter 3) in the Library of the member’s area at www.eurotransplant.org.

2.1.3.4 Clinical data

Results from clinical tests in the recipient, e.g. virology, immunology or histocompatibility, should be updated immediately in ENIS. For further information, please refer to the ENIS manual at www.eurotransplant.org.

If an HIV infection is confirmed, then the patient should be placed in urgency NT (temporarily not transplantable) until a thorough case evaluation has been performed.

2.1.3.5 Death on the waiting list

If a patient dies while listed on an ET waiting list, then the date and cause of death must be entered in ENIS within 72 hours after notice to the transplant center. For further information, please refer to the ENIS manual (chapter 3) in the Library of the member’s area at www.eurotransplant.org.

Timely updates in ENIS are important in order to exclude this transplant candidate from future matching procedures, thus avoiding unnecessary offers.

2.1.3.6 Removal from the waiting list

If a patient is removed from an ET waiting list for reasons other than death or transplantation, then the date and cause of the removal must be entered in ENIS within 72 hours after the removal. For further information, please refer to the ENIS manual (chapter 3) in the Library of the member’s area at www.eurotransplant.org.

Timely updates in ENIS are important in order to exclude this transplant candidate from future matching procedures, thus avoiding unnecessary offers.

All accumulated waiting time is deleted, except for recipients awaiting a kidney transplant for which the time on dialysis is counted as waiting time, provided that the dialysis is not interrupted for more than 90 days.

2.1.3.7 Transplant registration

After a patient is transplanted, the transplantation must be registered in ENIS, including date and time of the transplantation. For further information, please refer to chapters 2.1.9 and 2.2.3 in this manual and the ENIS manual (chapter 6) in the Library of the member’s area at www.eurotransplant.org.

2.1.3.8 Registration by ET duty desk

The ET duty desk will only list patients on, or remove patients from an ET waiting list, if it concerns patients that are or were in urgent need of an organ transplant, i.e. High Urgent
In case of removal, information on the date and cause for removal must be sent to the ET duty desk in writing.

In all other cases, registrations or removals must be performed by the transplant center itself.

2.1.3.9 Transfer of a patient

If a patient needs to be transferred to another ET transplant center, one of the centers must contact the ET medical administration by fax (see Forms at www.eurotransplant.org).

All accumulated waiting time is retained after the transfer.

2.1.3.10 Registration for a re-transplant and after removal

If a patient is registered for a re-transplant or after removal from the waiting list for reasons other than death, only the waiting list procedure is required. It is not necessary to repeat the initial registration procedure. Date and cause of failure of the previous transplant(s) must be entered in ENIS. If the patient was transplanted in a different center, then the new center will take over the follow-up of the previous transplant(s).

For further information, please refer to the ENIS manual (chapter 3) in the Library of the member’s area at www.eurotransplant.org.

2.1.4 Financial aspects

2.1.4.1 First Transplantation

Any patient registered on an ET waiting list for an organ transplantation will generate an invoice.

2.1.4.2 Re-transplantation

If the patient is registered for a re-transplant, a new invoice is generated.

2.1.4.3 After removal

If the patient has been removed from an ET waiting list for other reasons than transplantation, and is then registered again on a waiting list, with no organ transplantation in between, then no new invoice will be generated.

2.1.4.4 Multi-organ transplantation

If the patient is registered for a multi-organ transplantation, an invoice is only generated for one organ.

2.1.4.5 Consecutive transplantation with a different organ

If a patient received a transplant and is later registered on an ET waiting list for an organ other than the one transplanted, then an invoice is generated for this new organ.
2.1.4.6 Living donor organ transplantation

If a patient is registered on an ET waiting list for a post-mortem organ transplantation, and is then transplanted with an organ from a living donor, then the registration fee is not reimbursed.

2.1.4.7 Deviant national agreements

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<td>Germany</td>
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<td>Nederlandse Transplantatie Stichting (NTS)</td>
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2.1.5 Non-resident recipients

2.1.5.1 Background

The matter of non-resident transplantation is in most regards independent of the number of such transplants. The real concern of non-resident transplantation is that it might influence the social acceptance of donation of organs and transplantation in general. This could endanger the willingness to donate organs.

The non-resident policy is based on the following basic considerations:

- Any limitation of non-resident transplantation (other than a strict 0% rule) is arbitrary.

- A strict 0% non-resident rule is according to the opinion of several recently published documents not in line with European legislation and general ethical principles.

- Within the ET countries there is, with the exception of Belgium, Croatia and Slovenia, no legislation in the area of non-resident transplantation. Even in Belgium transplantation of non-residents is possible (based on a Royal decree and individual decisions taken in the Ministry of Health).

- Providing transplants to patients from outside a country/organ exchange organization (OEO) should not undermine the country’s / OEO’s ability to provide transplant services for its own population (Istanbul declaration, Madrid resolution). For further information please see section 2.1.5.2.

- It has never been and can also not be the role of Eurotransplant to enforce any non-resident rule, as Eurotransplant has no legal power.

- Eurotransplant should provide transparency in the allocation process also with regard to the transplantation of non-residents.

The aim of this policy is therefore:
To provide clear definitions regarding residency status for the data collection by ET;
- To promote enhanced transparency regarding the transplantation of non-resident patients within ET;
- Ultimately to analyze whether the transplantation of non-residents undermines the ability of the ET countries to provide transplantation services for its own population.

The policy is a normative, not a legal rule, for which reason it cannot be legally enforced.

2.1.5.2 Declaration of Istanbul;
Definitions of ‘Travel for Transplantation’, ‘Transplant Tourism’ and ‘Organ trafficking’

According to the Declaration of Istanbul
- **Travel for transplantation** is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes.
- Travel for transplantation becomes **transplant tourism** if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population.
- **Organ trafficking** is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation.

2.1.5.3 ET Non-resident policy

2.1.5.3.1 Deceased donors

Travel for deceased donor transplantation from countries outside the ET region shall not be actively supported by Eurotransplant transplant centers, for example by advertising deceased donor transplants outside ET, cooperation with organizations doing so or by in any other way encouraging possible recipients to travel for transplant to an ET transplant center.

Eurotransplant is opposing transplant tourism as the transplantation of non-residents within Eurotransplant may undermine the ET country’s ability to provide transplant services for its own population, ET condemns organ trafficking. ET transplant centers shall abstain from any activity involving transplant tourism and organ trafficking.

The respective national regulations apply concerning the access to the waiting list of non-residents. ET can and will not have its own rules concerning this aspect. In order to achieve the best possible transparency regarding the transplantation activities ET will report on an annual basis on the transplantation of non-residents. This means that ET reports per transplant center all transplants
according to the different categories of nationality and residency status defined below. In addition ET will continue to report on all transplants performed in the framework of a twinning agreement separately.

These reports will be based on self-reporting this type of data by the transplant centers. Therefore the transplant centers have the responsibility to report the nationality and residency status correctly. ET recognizes that relying on self-reporting by the transplant centers has its limitations but given the limited legal role and responsibility of ET it is felt that this approach is appropriate. It is also in line with the self-reporting of other demographic patient data by the transplant centers to ET.

2.1.5.3.2 Living donors

Living donor transplantation in non-residents will not be included in the report. ET is not responsible for living donor selection. The responsibility for the complete living donor procedure lies with the transplant center.

Living donor transplantation with non-ET residents has to be in line with the respective national legislation and should comply with the ET recommendation on living donation (REC01.06).

When registering a living donor also in respect to the GDPR which came into force on 25th May 2018, the living donor also should give his/her consent for data use and sharing, as described in the registration procedure 2.1.2.

2.1.5.4 Background information nationality, residency and citizen

2.1.5.4.1 Nationality

Nationality and residency are not identical, but two different legal categories. To be a national of a given country implies that the person has the nationality (= holds a passport) of that country. In other words: a German national is someone with the German nationality/passport. That nationality can depend on:

a) Birth: in most countries a child gets the nationality of the parent(s); but some countries grant any child born in that country the nationality of that country, irrespective of the nationality of the parent(s).

b) Heritage: some countries grant persons the nationality of that country if they can trace back their origin to that country, even if they are not resident or born in that country.

c) Granted by the state: the nationality of a country can be conferred to a national of another country (on specific grounds).

2.1.5.4.2 Residency

Residency, in the legal sense, means that someone has the right of stay (legal residence) in a given country, irrespective of his nationality. Legal residence means that a person has officially been granted the status of (long-term) resident, because he fulfills certain criteria and has applied for this status.

2.1.5.4.2.1 EU-law on residency

The EU makes a distinction only between EU nationals and non-EU nationals. An EU national is any person who has the nationality of an EU member state, and consequently a non-EU national is any person who does not hold the nationality of an EU member state (a third country national). EU law ensures that EU nationals get equal
treatment throughout the Union (Principle of non-discrimination based on Article 10 of the Treaty on the Functioning of the European Union (TFEU) and on Article 21 of the Charter of Fundamental Rights of the European Union).

EU law makes a further distinction between non-EU nationals who are long-term residents (in an EU country) and those who are not long-term residents. EU Council Directive 2003/109/EC (of 25 November 2003) defines that a non-EU national can be granted the long-term residency status after 5 years of continuous legal residence (Periods of absence from the territory of the Member State concerned shall not interrupt the 5-year period and shall be taken into account for its calculation where they are shorter than six consecutive months and do not exceed in total 10 months within the 5-year period).

This directive applies to all non-EU nationals legally residing in the territory of an EU country. However, some categories of individuals are excluded because of their legally precarious situation or because they are resident on a short-term basis only (refugees and asylum seekers awaiting decision on their status, seasonal workers, students or persons doing vocational training, persons who are granted temporary protection). The crux is that all non-EU nationals with a legal long-term resident status shall enjoy equal treatment with EU-nationals (among others: welfare benefits, social assistance and health care insurance and care). Again, Directive 2003/109/EC approximates the laws of the EU to non-EU nationals with a long-term residency status (equal treatment).

2.1.5.4.2.2 Deviant national regulations on residency

In Belgium, Croatia and Slovenia a patient is considered a “resident” after 6 months of legal residence in the respective country.

2.1.5.4.3 Citizen and citizenship

Somewhat confusing are the terms ‘citizen’ and ‘citizenship’: they have no precise legal meaning. To be a Dutch citizen can mean that a person has the Dutch nationality (passport), but also that he is just resident in that country (= inhabitant). The same with citizenship: to have Dutch citizenship usually means that one has the Dutch nationality; but a person can be given the citizenship of Amsterdam, because of special merit to that city (= honorary citizenship), without having the Dutch nationality. It is better to use the general legal term ‘national’. (NB the term ‘EU citizen’ is often loosely used for anyone living (long-term or permanently) in the EU, but who does not necessarily also hold the passport of an EU member state).

2.1.5.5 Definition of ‘ET national’, ‘ET resident’ and ‘Non-ET resident’

2.1.5.5.1 ET national:

Eurotransplant defines an ‘ET NATIONAL’ as:
- All persons with a valid passport of one of the ET member states

2.1.5.5.2 ET residents:

Eurotransplant defines a recipient as ‘ET RESIDENT’ as:
a) All persons with the nationality of one of the ET member states, who are permanently or long-term resident (≥5 years) in one of the ET countries (but not necessarily the country of which he is a national); and

b) All persons who are non-nationals of an ET member state but have official long-term residency status (≥ 5 years residency) in one of the ET countries.

Reasoning: The underlying principle is that these persons will be potential contributors to the ET donor pool.

c) In the event that there is an active twinning agreement or other type of formalized, by the ET-Board approved cooperation between an ET center with a center, region or country outside ET, patients from this twinning center, region or country outside ET with the nationality of that country are counted as residents.

Reasoning: ET twinning agreements or other type of formalized, by the ET-Board approved cooperation, are based on reciprocity regarding organ donation and transplantation between the ET and the non-ET center, region or country and as such do not undermine the ability of the ET countries to provide transplant services to its own population.

The former ET policy that patients are considered to be ‘ET residents’ in the event of receiving a re-transplantation after having had their first transplant in an ET country, is no longer valid for new registrations on the waiting list.

2.1.5.5.3 Non-ET residents:

Eurotransplant defines a recipient as ‘NON-ET RESIDENT’ as:
- All persons that are not residents according to the above given definition

2.1.5.5.4 Deviant national regulations

2.1.5.5.4.1 Belgium

According to the ‘Royal Decree regarding the procurement and allocation of human organs’ (November 24, 1997), a non-resident person is defined as a person who has a nationality different from the Belgian, or one of the other ET countries, and/or who has no permanent address in Belgium, or one of the other ET countries.

Non-residents can only be listed on a Belgian organ-specific waiting list after approval of the Belgium ministry.

2.1.6 Monitoring general information

In order to achieve the best possible transparency regarding the transplantation activities ET will report on an annual basis per transplant center all transplants according to the different categories of nationality and residency status defined below. In addition ET will continue to report on all transplants performed in the framework of a twinning agreement separately.

These reports will be based on self-reporting this type of data by the transplant centers. Therefore the transplant centers have the responsibility to report the nationality and residency status correctly. ET recognizes that relying on self-reporting by the transplant centers has its limitations but given the limited legal role and responsibility
of ET it is felt that this approach is appropriate. It is also in line with the self-reporting of other demographic patient data by the transplant centers to ET.

2.1.5.7 Data collection and verification of residency status

At the time of registration, the following information will be collected:

a) **Nationality** of the recipient:
The transplant center has to provide information on the nationality of the recipient to Eurotransplant at the time of registration. For reporting the nationality of the recipient will be categorized by ET into:

- ET country
- EU country
- All other countries

*The nationality is to be verified by the transplant center based on the passport of the recipient. The nationality of the recipient can be updated prior to transplantation by the transplant center at any time.*

b) **Country of residence of the recipient**
The transplant center has to provide information whether the recipient resides in one of the ET countries. If the recipient has his residence in one of the ET countries, the country has to be specified and the duration of residency has to be reported using one of the following 3 categories:

- < 6 months
- between 6 months and 5 years
- ≥ 5 years

If the recipient does not have his residency in one of the ET countries, the transplant center has to provide information whether the recipient resides in one of the EU countries. If the recipient has his residence in one of the EU countries, the country has to be specified and the duration of residency has to be reported using one of the following 3 categories:

- < 6 months
- between 6 months and 5 years
- ≥ 5 years

If the patient does neither have his residency in an ET nor an EU country the name of the country of residence has to be provided.

*Long-term residence-status (> 5 years) is to be verified by the transplant center based on an official document of long-term residency. The country of residence and the duration of residency within one of the ET countries of the recipient can be updated prior to transplantation by the transplant center at any time.*

2.1.6 The HIV positive recipient

Prior to registration, potential recipients should be tested for Human Immunodeficiency Virus (HIV) antibodies according to Good Laboratory Practice. In case of a positive test result, he/she can be considered for organ transplantation, following a careful case by case evaluation.
2.1.7 Requirements for the request or discontinuation of a transplantation program

Installation of a new transplantation center and/or program
- An official request must be submitted by mail addressed to Eurotransplant.
- Request must contain legal documents with written and signed approval by the national authorities.
- Request must contain a letter with specifics regarding which organ, waiting list management, procurement arrangements, planning details, etc.

Shutting down of an existing transplantation program
- An official notification must be sent by mail addressed to Eurotransplant.
- Notification must contain a letter with specifics regarding waiting list management and continuation of follow up.

Temporary discontinuation of a transplantation program
- An official notification must be sent by e-mail addressed to Eurotransplant.
- Notification must contain a letter with specifics regarding the reason of discontinuation, expected duration, waiting list management, etc.
- Restart is only possible after approval of Eurotransplant.

Fusion of two existing transplantation programs
- An official request must be submitted by mail addressed to Eurotransplant.
- Request must contain legal documents with written and signed approval by the national authorities.
- Request must contain a letter with specifics regarding which organ, waiting list management, procurement arrangements, planning details, etc.

General notifications
- The new program must comply with the general Eurotransplant accession requirements as written on the member site.
- Requests must be submitted well in advance
- Implementation of a new transplant center into the system may take up to months.
- For additional questions, please send an e-mail addressed to the Board of Management via e-mail address secretariat@eurotransplant.org

2.1.8 Registration in more than one transplant center

2.1.8.1 Within ET

It is prohibited to register a patient simultaneously at two or more different transplant centers within the ET countries.

2.1.8.2 Outside ET

It is prohibited to register a patient simultaneously at one transplant center within the ET
countries and at one or more centers outside the ET countries.

2.1.9  Non-approved transplant centers

A transplant center must not list a patient on an ET waiting list if the center has no official approval by the competent national health authority allowing organ transplantations. Already registered patients must be transferred to an approved transplant center.

In case of force majeure, a transplant center must immediately contact the ET medical staff prior to any allocation and/or transplantation. The problem will be discussed with the chairman of the respective ET Advisory Committee, the ET medical director and/or the president of ET.

2.1.10  Registration of a transplantation

A transplant center must register organ transplantation in ENIS as soon as possible but no later than 72 hours after the transplantation. The registration of this transplantation (code T1, T2 or T3) will remove the patient from the ET waiting list and assign the Follow-up code (FU).

In case of a re-transplantation, cause and date of graft failure of the previous transplantation must be entered in ENIS. Follow-up data can be entered directly in ENIS at any time. For further information, please refer to the ENIS manual in the Library of the member’s area at www.eurotransplant.org.

2.1.11  Follow-up

A transplant center must enter follow-up information in ENIS for transplantations performed either in this center or for recipients transplanted elsewhere and transferred to this center. For further information, please refer to the ENIS manual (chapter 6) in the Library of the member’s area at www.eurotransplant.org.

2.1.11.1  Immediate follow-up

The following data is asked in ENIS:
- Cold Ischemia Period (CIP): time between start of perfusion and moment the organ is kept at >4ºC (during transplantation or its immediate preparation);
- Second Warm Ischemia Period (or anastomosis time): time between end of CIP and complete re-vascularization;
- Initial graft function;
- Immunosuppressive regimen (induction therapy);
- Transplant technique.

2.1.11.2  Long-term follow-up

The following data is asked in ENIS:
- Graft function at 1 week, 1m, 3m, 6m, and once a year thereafter (or as of date recipient last seen) post-transplant;
- Maintenance and updates of immunosuppressive agents;
- Date(s) of graft rejection, histological confirmation of rejection, anti-rejection therapy;
- Date and cause of graft failure or death (if applicable);
2.1.11.3 Liver

2.1.11.3.1 HU Liver Study

The ET medical administration sends questionnaires for transplantations performed in urgency HU. The data requested comprises the pathological report of the explanted liver and graft and recipient status (1m, 3m, 6m and 12m post-transplant).

2.1.11.3.2 Liver transplants since 01.01.2006

All liver transplants since 01.01.2006, except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the liver follow-up procedure can be found in the Library of the member’s area at www.eurotransplant.org.

2.1.11.4 Kidney

2.1.11.4.1 Kidney transplants since 01.01.2006

All kidney transplants since 01.01.2006, except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the kidney follow-up procedure can be found in the Library of the member’s area at www.eurotransplant.org.

2.1.11.5 Heart

All heart transplants except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the follow-up procedure ‘Heart post-transplant follow-up package’ can be found in the Library of the member’s area at www.eurotransplant.org.

2.1.11.5.1 Dutch thoracic transplants

All thoracic transplants performed in the Netherlands are integrated into the NOTR.

The detailed description of the follow-up procedure ‘Heart post-transplant follow-up package’ can be found in the Library of the member’s area at www.eurotransplant.org.

2.1.12 Submission of data to international registries

Transplant-related data are submitted to (inter)national research registries in the field of organ transplantation with consent by the transplant center.

2.1.12.1 European Liver Transplant Registry (ELTR)

On request of a transplant centers, ET will send their follow-up data to the ELTR (www.eltr.org), documented consent from the individual patient is necessary.
2.1.12.2  *International Society for Heart & Lung Transplantation (ISHLT) Registry*

Follow-up data for thoracic transplantations are forwarded to the ISHLT in case the patient has given consent ([www.isHLT.org](http://www.isHLT.org)).

2.1.12.3  *Collaborative Transplant Study (CTS)*

ET and CTS ([www.ctstransplant.org](http://www.ctstransplant.org)) exchange data on all organ transplantations performed within ET, documented consent by the individual patient is necessary.

2.1.12.4  *MrQ Heart*

The clinical profile of all transplant candidates listed on the heart waiting list is integral part of ENIS since October 23, 2003. A patient’s profile is entered at time of initial registration and, from then on, at regular intervals. Evaluation is terminated either at time of heart transplant, or at time of removal from the waiting list for reasons other than heart transplant.

The detailed description of the registration procedure ‘Heart waiting list monitoring package’ can be found in the Library of the member’s area at [www.eurotransplant.org](http://www.eurotransplant.org).

2.1.12.5  *Nederlandse Orgaan Transplantatie Registratie (NOTR)*

Dutch transplant centers send all data on transplantations to the central database of the NOTR. The NOTR collects and manages the data and transfers it to ENIS and e.g. (international) transplant registries or governmental institutions. Documented consent is necessary.

2.1.12.6  *Austrian kidney transplantations*

Dr Kramar (Linz) collects all follow-up data for kidney transplantations performed in Austria (except Vienna) and transfers the data to Eurotransplant.

This database is planned to be integrated into ENIS. Further details will be provided in the future.

2.1.12.7  *German National Transplant Registry*

On November 18, 2016 the German transplant law was changed and a new national transplant registry was installed. Eurotransplant is obliged by German law to deliver data to the German transplant registry, but only in case the patient has given explicit consent.

2.1.13  *Virological screening after transplantation*

Eurotransplant recommends performing at least at 3 and 12 months post-transplant a screening for HIV, Hepatitis B and Hepatitis C.

2.1.14  *Donor-related disease transmission*

If a transplant center suspects or has evidence for a donor-related disease transmission (infection, malignancy etc.), the center should immediately inform the ET medical staff in writing.

The ET medical staff will subsequently evaluate the case together with the donor center and
will contact the other transplant centers that received either organs or tissues from this donor.

The transplant centers contacted are responsible to inform their recipients transplanted with either organs or tissues from this donor and to take appropriate measures.

2.1.15 Data release

An individual or organization can request in writing (English) donor or recipient-related data.

The ET Medical Staff reviews the request and, after approval, contacts the center(s) involved. The following information is forwarded without revealing a recipient’s identity:

- ET number, gender, age, primary disease and waiting time;
- transplant program;
- initial graft function.

This data release is covered by the physician’s declaration at the time of listing the patient on an ET waiting list.

2.1.16 Data privacy

A transplant center must adhere to the current national legislation on privacy and protection of personalized data when releasing data about patients.

2.1.17 Use of organs for other than transplantation

2.1.17.1 Discard

If an organ is not-transplantable, at time of procurement or upon arrival in the transplant center, respectively, the involved team must immediately contact the ET duty officers.

The discard of an organ(s) is discussed with the donor procurement organization or center and the transplant program(s) involved. Following this it is decided where the organ will ultimately be discarded. ET documents the location of the discarded organ.

2.1.17.2 Research

If a procured organ is not transplantable, it can be offered to an ET transplant research program whose project has been approved by an ET Advisory Committee and by the ET Board. Consent from the donor through the donor procurement organization or center is obligatory. ET documents the location of the research program.

For further information, please refer to the organ-specific chapters in this manual.

2.1.17.2.1 Pancreas

Islet transplant programs and pancreas research programs should keep a record of all accepted donor pancreata, as well as the ultimate disposition (research, discard, transplantation, bank).

This information should be sent to the secretary of the Pancreas Advisory Committee on a quarterly basis.
2.1.18 Violation of allocation rules

Violations of current allocation rules are reported by ET to the director of the transplant center involved, the chairperson of the national transplant society and the chairperson of the respective ET Advisory Committee.

The transplant center is asked to respond to this letter in due time explaining the reasons for the non-compliance.

Violations are further discussed during the ET Advisory Committee meetings.

2.1.18.1 Deviant national agreements

2.1.18.1.1 Germany

A copy of violation letters is sent to the chairperson of the Prüfungskommission of the Bundesärztekammer (BÄK).

2.1.18.1.2 The Netherlands

A copy of violation letters is sent to the Head of Medical Affairs of the Nederlandse Transplantatie Stichting (NTS).

2.1.18.1.3 Belgium

A copy of violation letters is sent to the chairperson of the Belgische Transplantatie Raad (BTR).

2.1.18.1.4 Croatia

A copy of violation letters is sent to the Ministry of Health and Social Welfare.

2.1.18.1.5 Hungary

A copy of violation letters is sent to the Hungarian National Blood Transfusion Service (HNBTS).
2.2 Living donor organ transplantation

Patients listed on one or more of the ET waiting lists awaiting a living donor organ transplant are not excluded from a single or multi-organ transplant from a post-mortem donor.

It is the sole responsibility of a transplant surgeon and/or physician to prepare a living donor transplant, i.e. donor screening and patient selection. The selection of living organ donors should follow the guidelines of the ET Ethics Committee, the European Society for Organ Transplantation (ESOT), the International Society for Organ Transplantation (ISOT), the Council of Europe as well as current national guidelines and/or laws on transplantation.

2.2.1 Domino organ transplantation

If a post-mortem donor organ is transplanted to a patient whose primary disease allows the use of his/her therapeutically explanted organ for a consecutive second transplant, then this patient is called a domino donor. A domino donor can be considered a living donor if this is in accordance with current national laws on transplantation and/or guidelines.

2.2.1.1 Domino heart

A domino heart donation exclusively occurs after combined post-mortem heart+lung transplants. This healthy heart can be used for a consecutive transplantation in a recipient who is chosen from the center’s own waiting list. If no suitable recipient is available, then this organ is reported back to the ET duty desk for patient-specific allocation. For further information, please refer to the ET manual chapter 6 in the Library of the member’s area at www.eurotransplant.org.

2.2.1.2 Domino liver

A domino liver donation e.g. occurs in a patient who is suffering from a non-cirrhotic metabolic liver disorder, e.g. Familial Amyloid Polyneuropathy (FAP) or Oxalosis. This compromised liver can be used for a consecutive transplantation in a recipient who is chosen from the center’s own waiting list. If no suitable recipient is available, then this organ is reported back to the ET duty desk for patient-specific allocation.

The genetic enzyme defect of the liver will only become clinically apparent in a second recipient long after the transplantation. Therefore, patients e.g. with a reduced life expectancy can be chosen as a recipient for such a liver, as the expected time until development of clinical signs resulting from the compromised liver organ might extend beyond the expected life expectancy of the recipient. For further information, please refer to the ET manual chapter 5 in the Library of the member’s area at www.eurotransplant.org.

2.2.1.3 Domino transplantation in Germany

Transplant candidates willing to accept a domino liver or heart must be indicated as such in the patient-specific donor profile in ENIS. They will then be allocated through to the modified allocation algorithm in accordance with the ‘Richtlinien zur Organtransplantation gemäß §16 TPG’ (www.baek.de).

2.2.2 Registration and waiting list
A patient can be listed on an ET waiting list, clearly indicating that he/she is exclusively awaiting a living donor organ transplant.

The registration procedures in ENIS are identical to those for patients awaiting a post-mortem organ transplant.

Upon registration, option ‘Yes’ for ‘Family transplant’ can be chosen. If ‘Yes’ is chosen, then this patient is excluded from any selection in a match procedure for a post-mortem donor organ.

### 2.2.2.1 Financial aspects

If ‘Yes’ is indicated for ‘Family transplant’ at the time of the patient’s registration on an ET waiting list:

<table>
<thead>
<tr>
<th>No invoice is generated in</th>
<th>Austria, Belgium, Hungary, Luxembourg, The Netherlands, Slovenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>An invoice is generated in</td>
<td>Germany</td>
</tr>
</tbody>
</table>

If the patient has first been registered on an ET waiting list for a post-mortem organ transplant, and is later registered for a living donor transplant by indicating ‘Yes’ for ‘Family transplant’, then the registration fee will not be returned.

If the patient has first been registered on an ET waiting list for a living donor transplant and is later indicated for post-mortem donor organ transplantation by changing “Family transplant” to ‘No’ to register the patient for a post-mortem organ transplantation only, then an invoice is generated. The transplant program must then provide all mandatory data necessary for the registration and allocation procedure for the post-mortem organ match programs.

It is recommended to register both the living donor organ transplantation and the living donor at the same time.

### 2.2.2.2 Deviant national agreements

#### 2.2.2.2.1 Germany

German transplant centers cannot indicate ‘Family transplant’, as all transplant candidates awaiting a post-mortem and a living donor organ transplant must prospectively be registered on a post-mortem ET waiting list in an active urgency.

All transplant candidates awaiting a living donor liver transplant are thus given the chance to receive a post-mortem organ before a living donor organ transplant.

### 2.2.3 Registration of a transplantation

A transplant center must register an organ transplantation in ENIS as soon as possible but no later than 72 hours after the transplantation. The registration of this transplantation (code T1, T2 or T3) will remove the patient from the ET waiting list and assign the Follow-up code (FU).

In case of a re-transplantation, cause and date of graft failure of the previous transplantation must be entered in ENIS. Follow-up data can be entered directly in ENIS at any time. For further information, please refer to the ENIS manual at [www.eurotransplant.org](http://www.eurotransplant.org).
Numbers for living donor transplants are added up to a center’s post-mortem transplant activity, in order to assign the correct number of votes for the center’s delegates in the annual Assembly Meeting (see ET Articles of Association).

2.2.3.1  Domino transplantation

In case of a domino procedure, the ET duty officers should be contacted to register the recipient of the post-mortem organ as the subsequent domino donor. In case the donor center does not have a recipient ET will generate a match list. The transplant resulting from the domino procedure is registered by the domino transplant center itself.
2.3 Forms

All forms can be found in section Forms of the Library of the member’s area at www.eurotransplant.org.