

Teaching and Training Agreement

This Teaching and Training Agreement is entered into by and between:

Stichting Eurotransplant International Foundation, Plesmanlaan 100, 2304 CH Leiden, the Netherlands, hereinafter referred to as “Eurotransplant”, duly represented hereto by Professor Dr. Bruno Meiser, President, and Professor Dr. X. Rogiers, Vice-President,

and

(national competent authority of non- Eurotransplant country)

.....*(name)*, hereinafter referred to as.....
established in.....*(address)*, represented
by.....*(name)*,*(position)*

(national competent authority of Eurotransplant country)

.....*(name)*, hereinafter referred to as.....
established in.....*(address)*, represented
by.....*(name)*,*(position)*

Collectively referred to as the “Parties”, or individually as the “Party”,

Whereas:

Eurotransplant International Foundation is an internationally recognized non-profit organization which mediates and coordinates organ exchanges for transplantation in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia.

The mediation of Eurotransplant is effectuated by the registration on a single waiting list of patients in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia and the central allocation of organs by Eurotransplant to patients in these countries.

Eurotransplant aims to promote, to support and to coordinate organ donation and transplantation as stated in her articles of association and by-laws. Therefore Eurotransplant member states, through their affiliated transplantation centers, express their willingness to cooperate with medical centers of non-Eurotransplant countries to support and to promote donation and transplantation of organs.

Considering that it serves the common interest of the Parties to strengthen and implement the collaboration among their authorities in an effort to facilitate the allocation and transplantation of deceased donor organs while optimizing and meeting the needs of specific types of patients, such as pediatric and highly sensitized patients donated organs;

Prerequisite for this Teaching and Training Agreement is a separate bilateral agreement between Eurotransplant and the organization in the non- Eurotransplant country responsible for the cross border exchange of organs (OEO as listed on page 1);

HAVE AGREED to the following terms laid down in this Teaching and Training Agreement (“the Agreement”)

Article 1. Purpose of the Agreement

The purpose of this Agreement is:

- to provide a framework for a training program in procurement, transplantation and post-transplant management of { insert type of organ} with the aim of establishing a successful and sustainable single or multi organ transplant program in the non- Eurotransplant center;
- this framework is divided into a non-clinical component and a clinical component. The non-clinical component comprises the infrastructural and equipment/technical requirements that the non- Eurotransplant center must satisfy in different stages of the teaching and training program. These requisites have been detailed in Appendix A. The clinical component spells out the guidelines and minimum requirements for the teaching and training program of the non- Eurotransplant center that have to be met. These requisites are specified in Appendix B;
- to define the rights and obligations of the Parties and ensure adequate information exchange between the Parties.

Article 2. Rights and Obligations

- 2.1. The Eurotransplant transplant center shall provide adequate organizational resources and training in procurement, transplantation and post-transplant management of { insert type of organ} to the non- Eurotransplant center in order to develop a successful transplantation program in compliance with the existing legal framework for organ donation and transplantation applicable in the respective countries.
- 2.2. During the term of this Agreement eligible patients who are resident in the country of the non- Eurotransplant center, shall be registered on the waiting list of Eurotransplant under the responsibility of the Eurotransplant transplant center after medical assessment and based on grounds of medical urgency. The non-Eurotransplant center carries the responsibility for pre-selection and referral of patients to the Eurotransplant transplant center.
- 2.3. The national competent authority of the non-Eurotransplant country guarantees that the non-Eurotransplant center registers patients on the waiting list in accordance to national transplant legislation.

- 2.4. All { insert type of organ} available in the Eurotransplant transplant center and the non-Eurotransplant center have to be reported and offered directly to the Eurotransplant office where these organs shall be allocated in accordance with the Eurotransplant Manual.
- 2.5. The number of patients from the non-Eurotransplant center transplanted in the Eurotransplant transplant center have to be in balance with the number of donor organs reported by the national OEO of the country of the non- Eurotransplant center and transplanted in an Eurotransplant transplant center.
- 2.6. The national competent authority of the non- Eurotransplant center shall guarantee compliance with the national legislation on organ donation and transplantation.

Article 3. Non commercialization

All Parties endorse the principle that transplantation may not give rise to financial considerations or material gain as laid down in the Declaration of Istanbul.

Commercialization and trafficking of organs are strictly prohibited.

Article 4.

All Parties mutually guarantee quality control, origin and traceability of organs exchanged. The non-Eurotransplant center provides follow-up data on transplanted patients to the Eurotransplant registry.

Article 5.

Screening or confirmatory microbiological and virology tests as well as HLA-typing of donors shall be performed using licensed tests and shall be performed by laboratories duly authorized by national authorities according to the national requirements

Article 6. Organ characterization

Organ characteristics shall meet the international standards accepted for organ exchange between national and international organizations according to what is established under EU-Directive 2010/53/EU and EU-Directive 2012/25/EU.

In case of cross border exchange of organs all information regarding donor and organ characterization is transmitted by the national competent authority of the country of origin to the country of destination.

Article 7. Serious adverse events and reactions

In accordance with article 7 of Directive 2012/25/EU, whenever a serious adverse event or reaction affects an organ or recipient of an organ that was exchanged cross-border, the involved Party shall report this immediately to the national competent authority of the country of origin.

Article 8. Language

All exchanged information is written in English.

Article 9. Financial aspects

- 9.1. The Eurotransplant transplant center and the non-Eurotransplant center are prohibited from receiving any payment that exceeds the justifiable fee for the treatment rendered.
- 9.2. Parties guarantee that the execution of this Agreement is not undertaken with an eye to any financial interest whatsoever and shall be under supervision of the national competent authority.
- 9.3. The Eurotransplant transplant center shall be entitled to charge the non- Eurotransplant center a reasonable fee for the training and teaching activities, specified in Appendix B.

Article 10. Confidentiality and privacy

The Parties shall ensure compliance with all relevant privacy regulations, the protection of confidentiality of individual records and other relevant legislation in their respective countries.

Article 11. Monitoring/audit

- 11.1. The respective Organ Advisory Committee of Eurotransplant shall accredit quality assurance procedures necessary to safeguard and enhance the standards of the teaching and training program and monitor the quality and progress of the teaching and training program.
- 11.2. The non- Eurotransplant center shall permit representatives of Eurotransplant, in relevant cases, to visit its center to perform an audit procedure.

Article 12. Reporting

Representatives of the Eurotransplant transplant center and the non- Eurotransplant center involved shall yearly report to the Board of management of Eurotransplant as well as to their national competent authority on the progress of the teaching and training program.

Article 13. Liability

- 13.1. Each Party shall indemnify the other Party for any loss or any liability arising from any action or omission by itself and its employees within the framework of this Agreement.
- 13.2. No Party shall be liable for delay or failure to fulfill its obligations under this Agreement if the delay or failure results from events of force majeure.

Article 14. Amendments

- 14.1 This Agreement may be amended by mutual consent between the Parties in writing at any time.
- 14.2 Should any provision of this Agreement prove to be invalid or incapable of fulfillment or lose its effectiveness due to later circumstances, the legal effectiveness of the remaining provisions is not affected.

Article 15. Applicable law and competent court

- 15.1 This agreement is governed by Dutch law.
- 15.2 Any difference or dispute concerning the interpretation or application of this Agreement shall be settled by means of consultation and negotiation between representatives of the Parties.

Article 16. Termination

- 16.1 This Agreement may be terminated by either Party at any time and for any reason upon written notice to the other Party or Parties concerned.
- 16.2 After termination of this Agreement neither Eurotransplant nor the Eurotransplant transplant center has any obligation towards the non- Eurotransplant center.

Article 17. Entry into force and duration

- 17.1 This Agreement shall enter into force on the first day after its signing and shall continue for a period of <...> years.
- 17.2 Eurotransplant can decide to prolong this Agreement upon the expiration of the term mentioned in 17.1 if this is necessary for successfully completing the local teaching and training program.
- 17.3 The Agreement shall automatically end after 3 years.

Signed by the Parties:

Eurotransplant-affiliated transplant Center Non- Eurotransplant Center

Name

Function

Date

Signature

**National Competent Authority of the non-
Eurotransplant country**

**National Competent Authority of
the Eurotransplant country**

Organization

Name

Function

Date

Signature

**Approval on behalf of the Board of
Eurotransplant**

Name

Function

Date

Signature