



Data Policy

Eurotransplant International Foundation



Table of content

- 1. INTRODUCTION 4**
- 2. PURPOSE AND SCOPE OF DATA POLICY EUROTRANSPLANT 4**
 - 2.1. Main data categories5
 - 2.2. Out of scope5
- 3. GOVERNANCE 6**
 - 3.1. Organizational structure.....6
 - 3.2. Process6
 - 3.3. Accountability and transparency6
- 4. INFORMATION SECURITY 7**
 - 4.1. Objective7
 - 4.2. Applicable legislation7
 - 4.3. Information and quality7
 - 4.3.1. Shared responsibilities7
 - 4.3.2. Basic principles information security7
- 5. Principles data policy Eurotransplant 8**
 - 5.1. Introduction8
 - 5.2. Principles.....8
 - 5.2.1. Access9
 - 5.2.2. Identifying purposes9
 - 5.2.3. Accuracy of data9
 - 5.2.4. Consent9
 - 5.2.5. Safeguards10
 - 5.2.6. Accountability10
- 6. DATA COLLECTION AND PROCESSING10**
 - 6.1. Data collection10
 - 6.2. Data processing10
- 7. DATA RETENTION AND DISCLOSURE11**
- 8. AUDITS12**
 - 8.1. Privacy audits.....12
 - 8.2. Compliance monitoring12
- 9. COMPLAINTS12**
- 10. DEFINITIONS12**

Confidential

This document is made available subject to the condition that the receiver will neither use nor disclose the contents except as agreed in writing with the copyright owner. Copyright is vested in Eurotransplant International Foundation, Leiden

© Eurotransplant International Foundation. All rights reserved.

Neither the whole nor any part of this document may be reproduced or distributed in any form or by any means (electronic, mechanical, reprographic, recording or otherwise) without the prior written consent of the copyright owner.

1. INTRODUCTION

Eurotransplant is a non-profit organization which facilitates patient-oriented allocation and cross-border exchange of deceased donor organs. Active for transplant centres and their associated tissue typing laboratories and donor hospitals in eight countries, Eurotransplant ensures an optimal use of donor organs.

The operations and activities of Eurotransplant are guided by the following principles: transparency, objectivity, reliability, accountability and validity of allocation criteria.

Information is an operating asset which, just like other important operating assets, is of value to the organization. Proper management of data contributes to the improvement of data quality and integrity. Transplant centres, health insurance companies and other health care stakeholders are actively engaging in the use, exchange and reporting of electronic health information. Due to this increasing interconnection, data is exposed to a rising number and wider range of threats and weaknesses. Therefore, effective data and information management and the protection of privacy are imperative to a meaningful use of health information systems.

Data can present itself in many different ways. The data may be printed out, sent out by fax or written down on paper, stored electronically, sent by mail or electronic media, shown on film or exchanged verbally. Data must always be protected in a suitable manner, taking the way of sharing or storage method into account.

Disruptions to the provision of data and the resulting in data loss can be prevented or at least limited by using a suitable set of control measures, including policies, working methods, procedures (SOP), organizational structures and software and device functions.

Goal of this document is to combine structure and publish a range of policies, procedures and rules with regard to management, usage and accessibility of data in the Eurotransplant information systems.

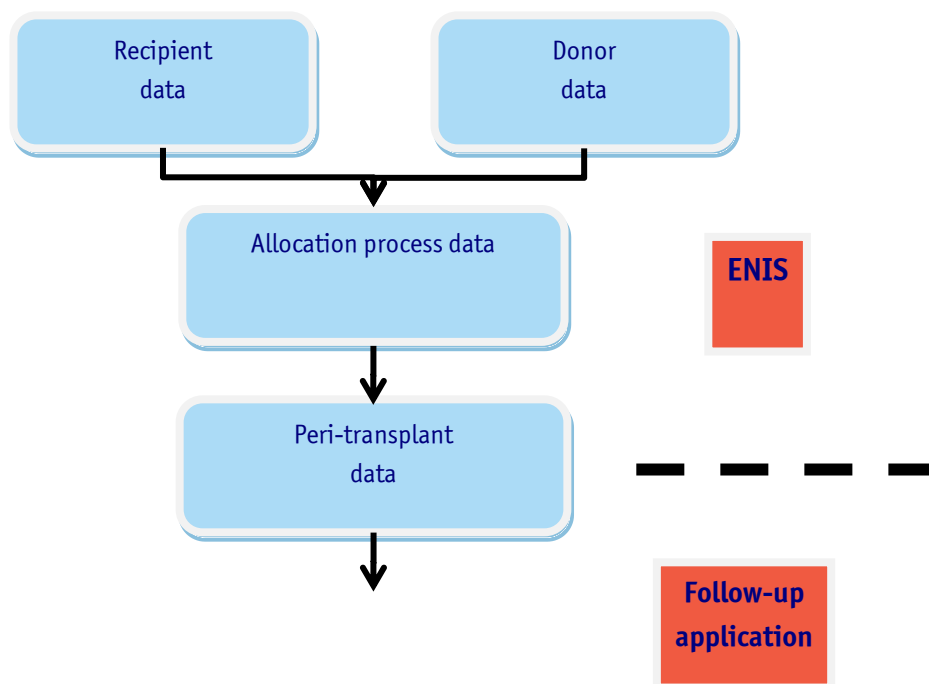
The European Commission plans to unify data protection within the European Union (EU) with the General Data Protection Regulation. This regulation is expected to be adopted in 2015 and enforced from 2017. The requirements of this regulation shall have to be implemented into this policy in due time.

2. PURPOSE AND SCOPE OF DATA POLICY EUROTRANSPLANT

The aim of this policy is to protect the privacy of individuals and ensure the quality and integrity of the electronic health information within Eurotransplant.

This document sets out how Eurotransplant aims to meet its legal obligations and requirements concerning the security and confidentiality of individually identifiable health information.

This policy covers, but is not limited to, personal health information in any form, including print, electronic, audiovisual and archived data.



Personal information is any information that relates to a living individual, held in any format, and where that individual can be identified from the data contents or from the data contents in combination with other information in the possession of Eurotransplant.

2.1. Main data categories

In order to systematically approach the different types of information in the Eurotransplant processes, an inventory has been made to categorize the data. Important parameters for categorization are whether the data contain confidential, identifiable (medical, personal) information, the purpose for which Eurotransplant gathers these data and with which third parties the data are being shared.

Based on the matrix the following main data categories can be distinguished. These categories are used as basis for this data policy.

- Donor data
- Recipient data
- Waiting list data
- Allocation data
- Peri-transplant data
- Long term follow-up data
- Financial data related to primary processes

2.2. Out of scope

The categories mentioned below are important for Eurotransplant to manage the organization. Policy on these data is incorporated in the Eurotransplant Quality Manual and out of scope for this data policy.

- Internal financial processes: payroll, accounts payable, accounts receivable.
- Human resource processes: all processes related to recruitment, development and management of employees.

3. GOVERNANCE

3.1. Organizational structure

Eurotransplant is a non-profit international organization that facilitates allocation and cross-border exchange of organs at the service of its member states. The international collaborative framework includes all transplant centers, tissue-typing laboratories and hospitals where organ donation and transplantation take place. Eurotransplant is a foundation governed by Dutch law. Its mandate is determined pursuant to a cooperation agreement between Eurotransplant and the individual member states.

Eurotransplant is committed to respecting personal privacy, safeguarding confidential information and ensuring the security of personal health information within its custody.

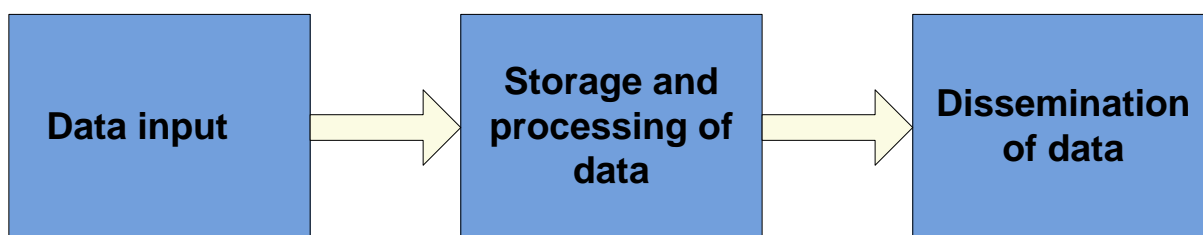
The responsibility for privacy and security ultimately reside with the Board of Eurotransplant who has formally delegated these functions at an operational level to the General Director of Eurotransplant, who is responsible for the day-to-day operations within Eurotransplant.

The General Director is supported in carrying out his responsibilities by the members of the Management Team. All Eurotransplant employees play an important role in the privacy and security of the data storage at Eurotransplant.

3.2. Process

Eurotransplant collects personal health information from healthcare organizations and professionals which are directly involved in the process of organ donation and transplantation. Eurotransplant uses this information for the execution and reporting on its performance of its role in these processes. The information is also used to improve the allocation process, allocation development and scientific research.

Process flow:



3.3. Accountability and transparency

Eurotransplant aims to provide a structure which promotes a culture committed to safeguarding the privacy and security of patient, medical and research information.

Eurotransplant is committed to comply with the Dutch Data Protection Act. This Act regulates the way in which personal information is handled from collection to use and disclosure, storage, accessibility and disposal.

All employees of Eurotransplant are accountable to protect privacy and confidentiality of personal information. Eurotransplant has designated a Privacy Officer who is responsible for the incorporation of privacy principles into the day-to-day-business, developing appropriate processes to educate employees and complying with applicable privacy legislation on an ongoing basis.

Eurotransplant is open and transparent about its privacy policy and procedures with respect to the management of personal health information by publishing all relevant documents on its website.

4. INFORMATION SECURITY

4.1. Objective

The main goal of information security at Eurotransplant is:

"to offer a framework of policy principles regarding the exclusivity, integrity and availability of the information provision, in the course of which a balanced (effective and efficient) system of interconnecting measures is developed in order to execute the provision of information in all processes without deviations and to protect it against internal and external threats."

4.2. Applicable legislation

The legal basis of information security is derived from both relevant national legislation and the legislation of the member states affiliated to Eurotransplant. In procedures and manuals, Eurotransplant has laid down how its employees should apply these rules in practice.

Eurotransplant complies with the prevailing organ transplant legislation of its affiliated member states for national donors and recipients in each of those countries.

Eurotransplant processes the personal health information obtained within the framework of the aforementioned process in a way that complies with the Dutch Personal Data Protection Act and the applicable national legislation.

4.3. Information and quality

4.3.1. Shared responsibilities

The Eurotransplant Computer System (ECS) facilitates the exchange of personal health information between health care providers (hospitals, doctors and tissue typing centers) and Eurotransplant with respect to its role within the process of organ transplantation.

The Eurotransplant organization has been contractually entrusted by the Competent Authorities of its member states with the custodianship, processing and administration of the personal health information to be disclosed by the healthcare providers to the ECS. The collection of data is limited to that what is necessary for identified purposes and in accordance with the procedures laid down in the Eurotransplant Manual.

4.3.2. Basic principles information security

Eurotransplant is responsible for designing and maintaining procedures for the safekeeping and stability of the data entrusted to Eurotransplant's custodianship.

The Eurotransplant Information Security Policy¹ states the following basic principles concerning the protection of data:

- Eurotransplant uses confidential information (legal term: special personal data). This requires employees of Eurotransplant to process this information in a specific manner.
- The security must comply with the applicable legislation, particularly with the Dutch Personal Data Protection Act.
- Information is accessible only to individuals who are authorized to this information based on appropriateness of their roles and intended use.
- Valuation of information: the employees of Eurotransplant are aware of the value of personal information used in its processes and act accordingly. How information is treated is determined by its use during the process.
- Employees are trained in how to treat information within the process they participate in when performing their duties.
- The systems of Eurotransplant comply with the security policy and security standards of the organization.
- The rules and agreements regarding information security that apply to employees of Eurotransplant also apply to affiliated third parties with whom a Shared Services agreement has been concluded.
- Eurotransplant has ownership of all the information and software products developed within the scope of its activities.
- Eurotransplant safeguards that data is strictly processed according to Eurotransplant procedures, and
- Eurotransplant asks for proof of appropriate information security measures at / by third parties. Affiliated third parties who use the Eurotransplant information systems are responsible for the integrity of the information they disclose to Eurotransplant.

5. Principles data policy Eurotransplant

5.1. Introduction

These principles are expected to guide the actions of all individuals and entities that participate within the Eurotransplant Computer System (ECS) for the purpose of electronics exchange of individually identifiable health information.

5.2. Principles

Eurotransplant supports and complies with the following principles of the Dutch Data Protection Act:

- *Personal data shall be processed fairly and lawfully;*
- *Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or purposes;*
- *Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed;*
- *Personal data shall be accurate and, where necessary, kept up to date;*
- *Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes;*

¹ ET Information Security Policy updated August 2014 ACTUEEL

- *Personal data shall be processed in accordance with the rights of data subjects under the Act;*
- *Appropriate technical measures shall be taken against unlawful access, loss of or damage to personal data;*
- *Personal data shall not be transferred to a country outside the Economic Economic Area (EEA) unless that country ensures an adequate level of data protection.*

5.2.1. Access

Eurotransplant has appropriate procedures in place to grant authorized access to its employees and third party users to the ECS insofar required to perform their official duties.

Eurotransplant prohibits the access to or use of more personal health data than is reasonably necessary to meet the identified purpose.

As Eurotransplant is not the primary data collector, all requests for access to or corrections of an individual's health record will be directed to the health care provider directly involved in their treatment.

5.2.2. Identifying purposes

Eurotransplant collects identifiable health information of patients from transplant centers and uses this information for the performance of its tasks as described in the ET Basic Mandate.

The purposes for which the data is collected are documented in the Eurotransplant Privacy Regulation. The processing operations of personal data have been notified to the Dutch Data Protection Authority (Dutch DPA) pursuant to the Dutch Data Protection Act.

Data which are disclosed to Eurotransplant and fall outside the purposes identified for data collection, will be returned or destroyed by Eurotransplant.

5.2.3. Accuracy of data

Eurotransplant takes reasonable steps to ensure that the personal health information is complete, accurate and kept up-to-date to the extent necessary for the intended purpose and activities related to organ transplantation or allocation development.

Eurotransplant is responsible for establishing a data quality program which enables the authorized users of ECS to verify the consistency and plausibility of the data entered into the Eurotransplant information systems. The authorized users are responsible for the submission of data and the correctness of the data into ECS.

Eurotransplant shall correct the data, exclusively upon written request of the authorized user. The authorized user is responsible for the data changes regardless of who performs these changes. The written request for change of data will be stored in the ECS.

Procedures for collecting data to and changing data in the ECS are described and maintained by Eurotransplant in the Eurotransplant Manual.

5.2.4. Consent

Eurotransplant uses identifiable health information disclosed to her by primary data collectors and as such has implied consent (e.g. treatment agreement) when providing allocation services at the request of the healthcare providers.

Eurotransplant provides healthcare providers with information regarding the authority and purpose for the collection, use and disclosure of personal health data by Eurotransplant.

For all use of data other than providing allocation services, Eurotransplant obtains an individual's consent before the collection, use or disclosure of identifiable information. Such consent may be explicit or implied where permitted by law.

5.2.5. Safeguards

Eurotransplant has adopted appropriate technical and organizational measures against unauthorized or unlawful processing, accidental loss or destruction or damage of personal health data.

The implementation of changes and of additions to the data base definition and system functionality are the responsibility of Eurotransplant in cooperation with the transplant centers.

Eurotransplant uses confidentiality agreements to reinforce employees and third parties understanding of their responsibility to protect personal information.

Eurotransplant requires that all its employees are aware of the importance of maintaining the confidentiality of personal health information through providing information on privacy and training programs.

5.2.6. Accountability

All necessary and sufficient administrative procedures included but not limited to those legally required, are to be performed by the authorized users. All data entrusted to the Eurotransplant information systems must meet these requirements.

Eurotransplant is responsible for ensuring that personal health data within its custody is managed in accordance with applicable privacy legislation.

Compliance with this policy shall be a part of any contract with a third party that may involve access to the ECS.

6. DATA COLLECTION AND PROCESSING

6.1. Data collection

Eurotransplant is currently gathering personal identifiable information on:

- patients listed on the waiting list;
- donors reported to Eurotransplant;
- all relevant steps of the allocation process (offering/acceptance/decline/procurement);
- transplantations;
- follow-up of transplants (registry).

6.2. Data processing

Eurotransplant will only use or disclose personal identifiable information for which it was collected, for any other purpose solely with the consent of the individual or as permitted by applicable law.

Eurotransplant will not use and disclose personal identifiable information if de-identified or aggregated information will serve the same purpose.

As a basic rule Eurotransplant obtains an individual's consent before the collection, use or disclosure of personal identifiable information. Such consent may be explicit or implied where permitted by law.

According to the Data Protection Act processing of personal data is permitted if:

- the data subject has unambiguously given his prior consent thereto;
- the processing is necessary for the performance of a contract to which the data subject is party;
- the processing is necessary in order to comply with a legal obligation to which the data controller is subject;
- the transfer is necessary in order to protect the vital interests of the data subject;
- the transfer is necessary or legally required in order to protect an important public interest; or
- the processing is necessary for upholding the legitimate interests of the data controller or of a third party, to whom the data is supplied, except where the interests or fundamental rights and freedoms of the data subject, in particular the right to protection of individual privacy, prevail.

In addition, personal data may not be further processed in a way incompatible with the purposes the data was collected.

Whether further processing is incompatible depends on different circumstances, such as:

- the relationship between the purpose of the intended processing and the purposes for which the data originally was obtained;
- the nature of the data concerned;
- the consequences of the intended processing for the data subject;
- the manner in which the data have been obtained; and
- the extent to which appropriate guarantees have been put in place with respect to the data subject.

Also, personal data may only be processed, where, given the purposes for which they are collected or subsequently processed, they are adequate, relevant and not excessive.

Eurotransplant has implemented defined access and user policies and procedures. Users requesting access shall be assigned to appropriate roles that have been clearly documented in the Eurotransplant Manual.

7. DATA RETENTION AND DISCLOSURE

All disclosures of identifiable data, de-identifiable data or aggregated data to individuals internally or externally must comply with this Data Policy and the Eurotransplant Data Disclosure Policy.

Eurotransplant retains all personal health data for as long as is necessary to fulfil legal requirements or patients needs.

Eurotransplant complies with the current legislation on the retention of data registrations within its organisation. A distinction is made between the registration of patient data for allocation purposes and other registrations. An overview of the retention periods of the different registrations has been documented in Eurotransplant Quality Manual.

Eurotransplant moves personal data which is no longer used to a separate storage device for long-term retention. Eurotransplant destroys all personal data, either in paper format or in electronic format, which is no longer required to fulfil the identified purpose, in a secure way.

Eurotransplant stores data obtained for use in research for as long as this is needed for the study. Data can be stored for a longer period that necessary for the relevant study only if stored in a database without identifying data and long as reasonably can be predicted that it will be needed for a health research project.

8. AUDITS

Eurotransplant has clearly defined the roles and responsibilities for data management and employees assigned to specific roles are held accountable for performing data management responsibilities as part of their daily work. The protection of personal data is standard in all business processes.

8.1. Privacy audits

Eurotransplant carries out annual audits as part of the periodical business processes. As part of the Information security management system, measures are taken to safeguard that data privacy is integral part of these audits. As Eurotransplant has no responsibility for the management of data security and privacy performed by its authorized users within their own organizations (i.e. in labs and transplant centres), Eurotransplant does not perform audits or on-site visits in these organizations.

The contractors of Eurotransplant (i.e. National Competent Authorities of the Eurotransplant member states) are allowed to perform audits at Eurotransplant to verify the levels of data security.

One of the key obligations the upcoming EU data Privacy Regulation will impose on organizations is a requirement to conduct Privacy Impact Assessments (PIA's) when processing of data presents specific risks to data subjects. Eurotransplant shall execute these PIA's when and as required.

8.2. Compliance monitoring

In the business processes Eurotransplant has taken measures to monitor compliance to rules and regulations on a detailed level. Monitoring compliance to national legislation and regulations is performed periodically by the privacy officer.

All employees of Eurotransplant are responsible for monitoring their personal compliance with the applicable policies of Eurotransplant. Any breaches must immediately be reported to the responsible manager.

This policy will be reviewed annually to ensure that it reflects current legislation and practices at Eurotransplant.

9. COMPLAINTS

All complaints about the collection, use, disclose and processing of personal health data by Eurotransplant will be handled by accordance with the Eurotransplant's complaints procedure.

10. DEFINITIONS

Authorized users healthcare organizations and professionals which are directly involved in the process of organ donation and transplantation on behalf of a transplant centre and who have been granted access to the ECS by Eurotransplant;

Collect	this means to gather, acquire, receive or obtain the information by any means from any source;
Consent	any freely given specific, informed and explicit indication of his or her wishes by which the individual, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to him or her being processed;
Data subject	the person the data pertains to;
Donor	a person who donates one or several organs, whether donation occurs during lifetime or after death;
ECS	the computerized information system that is managed by Eurotransplant in which information concerning donors, recipients and transplantation follow-up is entered in a uniform way in accordance with the ENIS Manual;
Personal data	any information relating to an identified or identifiable natural person;
Privacy impact Assessment	a risk management tool used to identify effects that a proposed or existing system or program may have on personal data;
Processing	any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, erasure or destruction;
Recipient	a person who receives a transplant of an organ;
Transplant centre	a healthcare establishment, a team or a unit of a hospital or any body which undertakes the transplantation of organs and are authorized to do so by the Competent Authority under the national regulatory framework of the member state concerned.