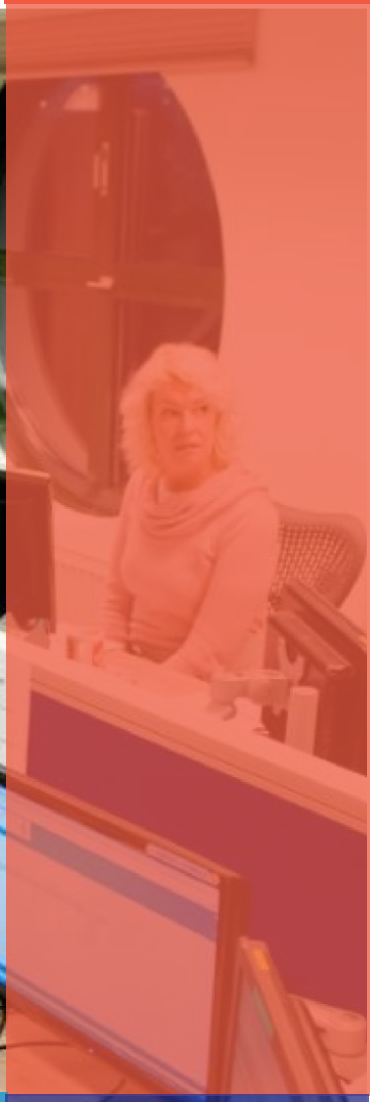
Eurotransplant

Data Disclosure Policy

Eurotransplant International Foundation



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1. Introduction

The basic principles on data confidentiality and security of personal health information of patients and (living) donors within Eurotransplant are laid down in the Eurotransplant Data Policy document. In addition to this policy, Eurotransplant has also defined principles on data use and -sharing which are embedded in a Data Disclosure Policy.

This Data Disclosure Policy sets out the principles and practice relating to the use and disclosure of data to third parties by Eurotransplant. It describes:

- procedures for the disclosure of data;
- the to this policy underlying principles.

2. Purpose

The purpose of this policy is to ensure that the use and disclosure of personal identifiable health information complies with applicable privacy laws. It sets out the principles and practice within Eurotransplant relating to the disclosure of data.

The purposes for which the data are collected by Eurotransplant are:

- execute allocation, being the core task of Eurotransplant;
- make the allocation process to authorized users and national authorities traceable and transparent;
- further improve the allocation process / rules;
- support scientific research;
- SAE/SAR handling.

3. Scope

This policy applies to:

1. the disclosure of data for planning and management purposes (including audits);
2. the disclosure of data for research purposes to Eurotransplant staff, centers or to third parties;
3. the disclosure of data to external requests for purposes other than research.

All access to personal health information must comply with applicable privacy laws and Eurotransplant's privacy policies and regulations.

4. Legal framework

Eurotransplant collects and processes personal identifiable information to provide allocation services to patients on its waiting list.
Eurotransplant also collects identifiable follow-up transplant information for international SAE/SAR legislation, quality analysis and allocation development purposes.

Eurotransplant is committed to comply with data protection legislation (GDPR – General Data Protection Regulation) and the Eurotransplant Data Policy which describes the responsibilities and provides principles and guidelines covering all aspects of processing personal information.
Information on the deceased is not protected by the GDPR, although the duty of confidentiality may require that sensitive medical information must be protected.

Anonymous data, in which the information which might identify an individual has been removed, is not considered personal data and is as such not covered by the GDPR.

The disclosure of personal identifiable data is a way of processing data. Under the GDPR this means that the rules on fair and lawful processing of data must be met. No personal identifiable information may be disclosed to any third party unless it is lawful to do so.

According to the GDPR the disclosure of personal health data is justified if:

- The data subject has unambiguously given his/her consent to the disclosure;
- The disclosure is required for the performance of a contract to which the data subject is party (e.g. the medical treatment agreement);
- If there is a statutory or legal obligation to disclose the data;
- The disclosure is necessary to protect the vital interest of the data subject;
- The disclosure is in the legitimate interests of Eurotransplant or of a third party to whom the data are to be disclosed and does not prejudice the rights, freedoms, or legitimate interests of the data subject.

The GDPR also allows under strict conditions personal data to be disclosed to third parties without the consent of the data subject for the purpose of scientific research or statistics provided:

- The research serves a public interest;
- The processing is necessary for the research or statistics concerned;
- It appears impossible or would involve a disproportionate effort to ask for consent;
- The processing for research purposes does not adversely affect the individual privacy of the data subject to a disproportional extent.

In all other cases the consent of the data subject is mandatory.

Eurotransplant shall not transfer personal identifiable information to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of individuals in relation to the processing of personal data. Anonymized research data can be transferred outside the European Economic Area.

5. Data Classification

Eurotransplant applies the following classification of data:

- Identifiable data: data which includes elements that directly identify an individual (e.g. name subject);
- Pseudonymized data: data which are considered to carry a high risk of identification whether or not combined with other data (e.g. ET number), for which the personal data are removed and replaced with a random unique identifier;
- Aggregated data: is information that relates to a group or category of consumers, from which individual consumer identities have been removed;
- Anonymous data: is data in which personally identifiable information is removed from the data set, so that the people whom the data describes cannot be identified.

5.1. Anonymous and aggregated data further explanation

Anonymous and aggregated data are both data that cannot be related to a natural person. Therefore, these data are not subject to the GDPR.

Anonymous data: Sharing data is possible based on anonymization. In case of sharing anonymized data Eurotransplant will remove all data that can directly identify an individual person. However, it is impossible to guarantee that anonymized data cannot be traced back to a single individual under normal circumstances. In this light ET will make sure that in any contract for data sharing with other organizations, it is mentioned clearly that no de-anonymization activities may be undertaken. This is described in the policy document "Eurotransplant decision regarding anonymization", which states that although ET will do its utmost to keep data anonymous, it is recognized that no guarantee can be given.

Aggregated data is information that relates to a group or category of consumers, from which individual consumer identities have been removed, that is not linked or reasonably linkable to any person, including via a device. In other words, it refers to the situation where multiple personal data points are combined so as to prevent the extrapolation of data as it relates to any particular person. However, the more statistics produced from the same underlying data, the more likely it is that the underlying data can be reconstructed from those statistics. Therefore, we use the threshold rule. According to the Dutch Privacy Authority, every subset needs to contain at least 5 entries. Research within the registries of Eurotransplant has shown that this can only be reached, by using maximum of 5 subsets. Because this is not enough for scientific research, Eurotransplant only delivers anonymous data.

5.2. Exchange of personal data with countries outside the EEA

Countries belonging to the EEA must comply with the GDPR. Therefore, transmission of data to these countries is allowed if it complies with one of the legal grounds. The EEA consists of the countries of the European Union and Norway, Iceland, and Liechtenstein. For countries that are not part of the EEA, the GDPR requires an adequate level of protection. The list of countries of which the European Privacy Council has decided to be adequate changes regularly. These countries can be found on the following **website**.

Due to Brexit, the United Kingdom no longer belongs to the EER. However, the European Council has decided that the UK belongs to the list of countries that have an adequate level of protection. Therefore, according to GDPR rules, transmission of data to the UK is allowed.

For the USA, another situation has occurred after the Schremm's 2 verdict. In July 2019 the European Court of Justice invalidated the Privacy Shield. The Privacy Shield Frameworks was designed by the U.S. Department of Commerce and the European Commission to provide companies on both sides of the Atlantic with a mechanism to comply with data protection requirements when transferring personal data from the European Union and to the United States in support of transatlantic commerce. Transferring personal data to the United States is still possible by using standard contractual clauses (SCC's). However, for each agreement for transfer of personal data, the data owner must assess the level of data protection of third countries and - where necessary – to take additional measures. To assess the level of data protection, the following steps must be followed:

1. Mapping of data transfers.
2. Assessing suitability of the transmission mechanism used.
3. Assessment of third country legislation.
4. Additional protective measures.
5. Procedural steps.
6. Evaluation and reassessment.

To assess every data transfer to the United States takes a lot of work. Therefore, the starting point of Eurotransplant for data transfer to the United States is that we only transfer data that is not subject to the GDPR. This means that can only be anonymous or aggregated data. Only if the requesting research center specifically needs personal data, meaning subject to the GDPR, Eurotransplant will assess the risks in the was described above.

6. Data collection

Eurotransplant is collecting personal identifiable information on:

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

Eurotransplant holds no more personal information about an individual than to the extent that is needed for the purpose of the information gathering. Eurotransplant applies measures to minimize the data set for a specific data disclosure.

7. Data Access

Eurotransplant distinguishes the following groups of users with access in the Eurotransplant Computer Systems to personal health information:

- Internal users (employees of ET);
- Eurotransplant authorized users: authorized members of the Eurotransplant community or otherwise linked to Eurotransplant; (including NCA's);
- Researchers (or registries) who get authorization based on an approved research protocol, based on the GDPR exception for research;
- Third parties like international registries for which the transplant center has obtained patient consent.

8. Data Disclosure to third parties?

Third parties can send in a request for data. A data request can originate from several requesters and be asked to support various types of scientific research. The demands vary per type of requester and type of research. In this chapter we have defined the following types of requests.

8.1. Statistics

When a request for data is for a statistical, epidemiological analysis or research, the data delivered will be anonymous. That means that the data cannot identify any natural person. In this case all data fields that may deliver a reference to a natural person have to be eliminated.

Due to the nature of these data (anonymous) there is no need for a contract with the data requester, there is no need for minimalization, as long as the data stays anonymous.

Summarized:

Statistical research	
Legal basis	Anonymous
Contract	No
Type of data	Anonymous
Data minimalization	No, as long as anonymization is guaranteed
EER/non-EER difference	No
Terms of use	Yes

8.2. Anonymous based registry exchange

The requester asks for the delivery data to a registry. However, the requester only needs an anonymous registry. In this case the data cannot be identified as a natural person.

Anonymous based registry exchange	
Legal basis	Anonymous
Contract	Specified agreements, based on template
Type of data	Anonymous
Data minimalization	No, as long as anonymization is guaranteed
EER/non-EER difference	No
Terms of use	No

8.3. Consent based registry exchange

The requester asks for the delivery of data to a registry. However, the data is only pseudonymized. That means that the data may identify a natural person. Therefore, specific details need to be defined and included in the contract.

Consent based registry exchange	
Legal basis	Consent and Scientific research exception (article 89 of the GDPR)
Contract	Specified agreements, based on template
Type of data	Pseudonymized

Data minimalization	Yes
EER/non-EER difference	Non-EER additional contract requirements, U.S. individually determined
Terms of use	Contract

8.4. Scientific research

For scientific research the legal basis is article 89 of the GDPR. In this case the generic contract is applicable and the scientific protocol is added to the contract.

Scientific research	
Legal basis	Scientific research, article 89 of the GDPR
Contract	Generic (general terms and conditions) with the Scientific protocol
Type of data	Pseudonymized
Data minimalization	Yes
EEA/non-EEA difference	For Non-EER recipients an adjusted contract, U.S. individually determined
Terms of use	Eurotransplant Study Agreement

8.5. Scientific cooperation

In scientific cooperation ETI and a scientific organization are working together. A contract with the specific agreements between both parties needs to be signed.

Scientific cooperation	
Legal basis	Scientific research, article 89 of the GDPR
Contract	Specific contractual agreements
Type of data	Pseudonymized
Data minimalization	Yes
EEA/non-EEA difference	For Non-EER recipients an adjusted contract, U.S. individually determined
Terms of use	More information will follow as soon as possible.

8.6. Internal research or evaluation

ETI performs research of an evaluation internally. The person doing this investigation is allowed to access the data, only a Non-Disclosure Agreement needs to be signed.

Internal research or evaluation	
Legal basis	Non-Disclosure Agreement
Contract	NA
Type of data	No limitation
Data minimalization	NA
EER/non-EER difference	NA
Terms of use	Publish only the statistics of the research

8.7. Evaluation by ETI Committee

Evaluation by ETI Committee	
Legal basis	Scientific research, article 89 of the GDPR
Contract	Generic (General terms and conditions) with the Scientific Protocol
Type of data	Pseudonymized
Data minimalization	Yes
EER/non-EER difference	NA
Terms of use	NA

8.8. Single Centre data

Centre own data	
Legal basis	Single Centre data (only data from your own centre)
Contract	No
Type of data	Only the data from the requesting centre
Data minimalization	Only the data from the requesting centre
EER/non-EER difference	NA
Terms of use	NA

8.9. NCA audits of transplant centers

NCA audits	
Legal basis	The performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
Contract	No
Type of data	No limitation
Data minimalization	No
EER/non-EER difference	NA
Terms of use	NA

8.10. NCA audits ETI

NCA audits ETI	
Legal basis	Contract ETI and NCA
Contract	No specific contract for the audit needed, only an Audit plan
Type of data	No limitation
Data minimalization	No
EER/non-EER difference	NA
Terms of use	NA

8.11. NCA data request

NCA data request	
Legal basis	Contract ETI and NCA or Law in the member country
Contract	Specific agreements in contracts
Type of data	Depends on the applicable law or contract
Data minimalization	Depends on the applicable law or contract
EER/non-EER difference	NA
Terms of use	NA

All data exchanges with NCA should be based on either a law or a contract. A current list of exchanges and their legal basis is available here [needs to be added].

9. DEFINITIONS

Authorized user	Healthcare organizations and professionals which are directly involved in the process of organ donation and transplantation on behalf of a transplant center 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, 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.
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 center	A healthcare establishment, a team or a unit of a hospital or anybody 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.

ANNEX 1: Procedure for data disclosure / presentations

Eurotransplant is committed to encourage innovative scientific research and develop follow-up data resources to improve organ allocation and transplant outcome.

This document outlines the procedure for accessing information contained in the Eurotransplant Computer System (ECS).

- Authorized Eurotransplant-users (including members of Eurotransplant Board and Advisory Committees): have access to or can request data available in ECS regarding:
  1) Their own center on a patient level:
     a. Patients on the waiting list;
     b. Donors offered to patients in their center during the allocation process, donors used for transplantation in their own center permanently (aggregated);
     c. Information on the allocation process for their recipients (peri-allocation report);
     d. Follow-up data including outcome data for their own center (Kaplan-Meier analysis).

  2) Other Eurotransplant centers on a center level with cumulative descriptive statistics on:
     a. registrations on the waiting list;
     b. waiting list dynamics;
     c. transplant activities.

  3) Follow-up data including outcome data on a national level, with the approval of the respective Eurotransplant Advisory Committee. A written request, including study proposal shall be sent to Eurotransplant and will be evaluated by the respective Advisory Committee.

  4) The representatives of an individual transplant program have access to the complete current overview of the national waiting list concerning the organs that are transplanted at the respective transplant center. In this list all patients from other transplant centers are anonymized.

- Public users have access to:
  1) Simple cumulative descriptive statistics (gender, age distribution, blood type).
  2) Detailed cumulative descriptive statistics on a national level (e.g. 'Annual Report').

- National authorities of the Eurotransplant member states have access to data down to patient level for donors from their own country and recipients from their own country (including the corresponding donors), if needed to address a specific question within the framework of their supervising role as specified in national law or bilateral contracts.

Data Disclosure Policy

Summary

		Registration	Donation	Transplantation	Follow-Up/ Outcome
Patient level		C	C	C	C
Center level	Basic[1]	M	M	M	-
	Detailed	C	C	C	C
Country level	Basic	P	P	P	M
	Detailed	M	M	M	C

1 Simple cumulative descriptive statistics (gender, age distribution, blood type, primary disease)

C: Authorized user within the Center / National Competent Authority

M: Individuals with access to the ET-Member site /Board/ Advisory Committees

P: General Public

Publication of ET-presentations on the Eurotransplant website

Based on the above outlined general rules for data-presentation and data-delivery the following regulations apply:

- Presentations / slides containing personal identifiable patient data shall not be published anywhere.
- Presentations / slides containing center-specific outcome data shall not be published anywhere.
- Presentations containing general country-specific / Eurotransplant-wide data may be published.

The Board or the respective Advisory Committees can decide not to publish individual analyses / slides or whole presentations on the Eurotransplant website.

ANNEX 2: Procedure for requesting data for scientific research

The purpose of this document is to outline the procedure which has been established by Eurotransplant to manage external requests for data for scientific research.

How to send in a request

The requesting party shall send a written request for data, when applicable accompanied with a study protocol to Eurotransplant. All documents should be in English.

Admission of a request

The medical staff of Eurotransplant will evaluate all submitted requests.

Conditions for receiving data

The Secretaries of the Advising Committee prepare a response to the requestor which can be an approval or rejection. In case additional conditions may be attached to the use of the data the requestor will be informed as well. The requesting party shall always respect the conditions of each request.

The following are the basic conditions for receiving data from Eurotransplant:

- The researcher shall execute the study in compliance with the guidelines on Good Clinical Practice, guidelines on authorship and publication of the International Committee of Medical Journal Editors (**www.icmje.org**), the Eurotransplant Data policy and Disclosure policy.
- Before publication the requestor will be required to send the outcome of the research to the respective Advisory Committee of Eurotransplant for information, or, when appropriate (the author is informed beforehand) for approval before admission for publication.
- If the data is no longer needed for the purpose the requestor received the data, the requestor is responsible for destruction of the data.
- The principal investigator is responsible for ethical approval of the study.

Eurotransplant Study Agreement

The main goal of the Study-Agreement is to be clear about the expectations and conditions with the sharing of data by Eurotransplant for a specific scientific purpose.

More information will follow as soon as possible.

Policy document anonymisation

See **link** for more information.

Costs

In case of more complex responses a fee may be charged. Requestors will be provided beforehand with a written estimate.