



Data Processing Agreement for ELTR/ELITA Registry studies

Between

Name and affiliation (Data Processor)

And

The European Liver Transplant Registry, a service of the European Liver and Intestine Transplant Association (ELTR/ELITA) (Data Controller)

1 Content

2 Data Processing Agreement preamble3

3 The rights and obligations of the ELTR/ELITA3

4 The Data Processor acts according to instructions.....4

5 Confidentiality4

6 Security of processing4

7 Use of Sub-Processors.....5

8 Assistance to the ELTR/ELITA5

9 Erasure and return of data.....6

10 Inspection and audit6

Appendix A8

Information about the processing8

Appendix B9

Instruction pertaining to the use of personal data.....9

B.1 Security of processing.....9

B.2 Storage period/erasure procedures.....9

Appendix C 10

Study synopsis

2 Data Processing Agreement preamble

1. This Data Processing Agreement sets out the rights and obligations that apply to the Data Processor's handling of personal data on behalf of the ELTR/ELITA.
2. This Agreement has been designed to ensure the Parties' compliance with [Article 28, sub-section 3 of Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC \(General Data Protection Regulation\)](#), which sets out specific requirements for the content of data processing agreements.
3. This Data Processing Agreement shall take priority over any similar provisions contained in other agreements between the Parties.
4. Three appendices are attached to this Data Processing Agreement. The Appendices form an integral part of this Data Processing Agreement.
5. 0 of the Data Processing Agreement contains details about the processing according to the ELTR/ELITA studies' regulations.
6. 0 of the Data Processing Agreement contains instructions on the processing that the Data Processor is to perform on behalf of the ELTR/ELITA (the subject of the processing), the minimum-security measures that are to be implemented.
7. Appendix C of the study synopsis contains background and aim of the studied subject, inclusion criteria and list of needed data.
8. The Data Processing Agreement and its associated Appendices shall be retained in writing as well as electronically by both Parties.

3 The rights and obligations of the ELTR/ELITA

1. The ELTR/ELITA shall be responsible to the outside world (including the data subject) for ensuring that the processing of personal data takes place within the framework of the General Data Protection Regulation.
2. The ELTR/ELITA shall therefore have both the right and obligation to make decisions about the purposes and means of the processing of personal data.
3. The ELTR/ELITA shall be responsible for ensuring that the processing that the Data Processor is instructed to perform is authorized in law.

4 The Data Processor acts according to instructions.

1. The Data Processor shall solely be permitted to process personal data on documented instructions from the ELTR/ELITA unless processing is required under EU or Member State law to which the Data Processor is subject; in this case, the Data Processor shall inform the ELTR/ELITA of this legal requirement prior to processing unless that law prohibits such information on important grounds of public interest, cf. [Article 28, sub-section 3, para a.](#)
2. The Data Processor shall immediately inform the ELTR/ELITA if instructions in the opinion of the Data Processor contravene the General Data Protection Regulation or data protection provisions contained in other EU or Member State law.

5 Confidentiality

1. The Data Processor shall ensure that only those persons who are currently authorized to do so are able to access the personal data being processed on behalf of the ELTR/ELITA. Access to the data shall therefore without delay be denied if such authorization is removed or expires.
2. Only persons who require access to the personal data to fulfil the obligations of the Data Processor to the ELTR/ELITA shall be provided with authorisation.
3. The Data Processor shall ensure that persons authorised to process personal data on behalf of the ELTR/ELITA have undertaken to observe confidentiality or are subject to suitable statutory obligation of confidentiality.
4. The Data Processor shall at the request of the ELTR/ELITA be able to demonstrate that the employees concerned are subject to the above confidentiality.

6 Security of processing

1. The Data Processor shall take all the measures required pursuant to Article 32 of the General Data Protection Regulation which stipulates that with consideration for the current level, implementation costs and the nature, scope, context and purposes of processing and the risk of varying likelihood and severity for the rights and freedoms of natural persons, the ELTR/ELITA and Processor shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk.
2. The above obligation means that the Data Processor shall perform a risk assessment and thereafter implement measures to counter the identified risk. Depending on their relevance, the measures may include the following:
 - a. Pseudonymization and encryption of personal data
 - b. The ability to ensure ongoing confidentiality, integrity, availability and resilience of processing systems and services.

- c. The ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident.

7 Use of Sub-Processors

1. The Data Processor shall meet the requirements specified in [Article 28, sub-section 2 and 4](#) of the General Data Protection Regulation to engage another processor (Sub-Processor).
2. The Data Processor shall therefore not engage another processor (Sub-Processor) for the fulfilment of this Data Processing Agreement without the prior specific or general written consent of the ELTR/ELITA.
3. In the event of general written consent, the Data Processor shall inform the ELTR/ELITA/ELITA of any planned changes about additions to or replacement of other data processors and thereby give the ELTR/ELITA the opportunity to object to such changes.
4. When the Data Processor has the ELTR/ELITA's authorization to use a sub-processor, the Data Processor shall ensure that the Sub-Processor is subject to the same data protection obligations as those specified in this Data Processing Agreement on the basis of a contract or other legal document under EU law or the national law of the Member States, in particular providing the necessary guarantees that the Sub-Processor will implement the appropriate technical and organizational measures in such a way that the processing meets the requirements of the General Data Protection Regulation.

The Data Processor shall therefore be responsible – based on a sub-processor agreement – for requiring that the sub-processor at least comply with the obligations to which the Data Processor is subject pursuant to the requirements of the General Data Protection Regulation and this Data Processing Agreement and its associated Appendices.

5. A copy of such a sub-processor agreement and subsequent amendments shall – at the ELTR/ELITA's request – be submitted to the ELTR/ELITA.
6. If the Sub-Processor does not fulfil his data protection obligations, the Data Processor shall remain fully liable to the ELTR/ELITA as regards the fulfilment of the obligations of the Sub-Processor.

8 Assistance to the ELTR/ELITA

1. The Data Processor, considering the nature of the processing, shall, as far as possible, assist the ELTR/ELITA with appropriate technical and organizational measures, in the fulfilment of the ELTR/ELITA's obligations to respond to requests for the exercise of the data subjects' rights pursuant to Chapter 3 of the General Data Protection Regulation. This entails that the Data Processor should as far as possible assist the ELTR/ELITA in the ELTR/ELITA's compliance with the right to be forgotten, rectification of data etc.

2. The Data Processor shall assist the ELTR/ELITA in ensuring compliance with the ELTR/ELITA's obligations pursuant to [Articles 32 to 36 of the General Data Protection Regulation](#) taking into account the nature of the processing and the data made available to the Data Processor listed in Appendix C, cf. [Article 28, sub-section 3, para f.](#)

This entails that the Data Processor should, considering the nature of the processing, as far as possible assist the ELTR/ELITA in the ELTR/ELITA's compliance with:

- a. the obligation to implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk associated with the processing.
- b. the obligation to report personal data breaches to the supervisory authority without undue delay and, if possible, within 72 hours of the ELTR/ELITA discovering such breach unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons.
- c. the obligation – without undue delay - to communicate the personal data breach to the data subject when such breach is likely to result in a high risk to the rights and freedoms of natural persons.
- d. the obligation to carry out a data protection impact assessment if a type of processing is likely to result in a high risk to the rights and freedoms of natural persons.

9 Erasure and return of data.

1. On termination of the processing services, the Data Processor shall be under obligation, at the ELTR/ELITA's discretion, to erase or return all the personal data to the ELTR/ELITA and to erase existing copies unless EU law or Member State law requires storage of the personal data.

10 Inspection and audit

1. The Data Processor shall make available to the ELTR/ELITA all information necessary to demonstrate compliance with [Article 28 of the General Data Protection Regulation](#) and this Data Processing Agreement, and allow for and contribute to audits, including inspections performed by the ELTR/ELITA or another auditor mandated by the ELTR/ELITA.
2. The ELTR/ELITA's inspection of sub-processors, if applicable, shall as a rule be performed through the Data Processor.
3. The Data Processor shall be required to provide the supervisory authorities, which pursuant to applicable legislation have access to the ELTR/ELITA's and Data Processor's facilities, or representatives acting on behalf of such supervisory authorities, with access to the Data Processor's physical facilities on presentation of appropriate identification.

On behalf of the ELTR/ELITA Data Controllers

Name:	Prof. René Adam	Name:	Prof. Wojtek Polak
Title:	ELTR General Manager	Title:	ELITA Chair
Date:		Date:	
Signature:		Signature:	

On behalf of the ELTR/ELITA Data Processors

Name:	
Affiliation:	
Study title:	
Date:	
Signature:	

Information about the processing

After receiving the dataset from ELTR I agree as follow:

1. The dataset is confidential, and it might be only used for the purpose of approved study by the ELITA Board.
2. No additional studies can be performed with the dataset.
3. The progress of the study must be reported every six months to the ELITA liaison person, ELITA secretary and ELTR.
4. If no progress has been made with the study for 2 years, the ELITA Board has the right to cancel the study.
5. The manuscript must be sent to ELITA liaison person before submission for publication.
6. The choice for a journal is made in agreement with the ELITA Board.
7. First, second and last authorship is for researchers performing the study; the third and the fourth position will be reserved for ELTR member and ELITA liaison person
8. The researchers are encouraged to include as many authors as possible (as allowed by the journal), one per center, according to the number of patients included in the study.
9. After the last author, the statement “for the European Liver and Intestine Transplant Association (ELITA)” has to be added.
10. All centers that have participated in the study with patients should be listed in a footnote or appendix, mentioning the program director and one of the collaborators.
11. A paragraph entitled “Acknowledgments” containing the text below should be added at the end of each ELTR manuscript: The ELTR is supported by a grant from Astellas, Novartis, Institut Georges Lopez, Sandoz, Chiesi and logistic support from the Paul Brousse Hospital (Assistance Publique – Hôpitaux de Paris). The Organ Sharing Organizations: the French ABM (Sami Djabbour), the Dutch NTS (Maaïke de Wolf), the Eurotransplant Foundation (Marieke Van Meel), the Spanish RETH (Gloria de la Rosa), the UK-Ireland NHSBT (Michael Daynes) and the ScandiTransplant (Ilse Duus Weinreich) are acknowledged for the data cross-check and sharing with the ELTR. These rules also apply when only a part of the published data is available in the ELTR database.

If the manuscript has been sent for publication or published without the acceptance of ELITA/ELTR, ELITA has a right to contact a journal where the manuscript has been sent and to remove this publication.

Instruction pertaining to the use of personal data

A.1 Security of processing

The level of security shall reflect:

That the processing involves a large volume of personal data which are subject to [Article 9 of the General Data Protection Regulation](#) on 'special categories of personal data' which is why a 'high' level of security should be established."

The Data Processor shall however – in any event and at a minimum – implement the following measures that have been agreed with the ELTR/ELITA:

1. Data can be transferred by the Data Processor in relation with scientific work and/or publications etc., however data must be completely anonymized or pseudonymized by Data Processor.
2. Data transfer of personal data is only allowed through secure encrypted channels.
3. User access control management must be implemented.
4. Access to data should require unique passwords of sufficient complexity and regular expiry.
5. Restrict access to personal data to those who need to know.
6. Multi-factor authentication, especially for remote access must be implemented.
7. Firewalls which are properly configured and using the latest software.
8. Regular software updates, if appropriate, by using patch management software
9. Real-time protection anti-virus, anti-malware and anti-spyware software is required.
10. Data must be securely protected during storage according to current legislation.
11. Transaction logging is required with user identification, type of event, date and time, success or failure indication, the origin of the event, and identity or name of affected data, system component or resource.

A.2 Storage period/erasure procedures

Personal data is securely stored with the Data Processor until the Data Processing Agreement is terminated or cancelled by one of the parties.

Study synopsis

Title:

Applicant:

Collaborators:

RATIONAL FOR THE STUDY

STUDY PROPOSAL

Patients and methods (list of needed ELTR variable)

Statistical analysis

Publications

Planned starting date of the study

