Legal memorandum on the structure forming the basis of the services which Scandiatransplant and Region Central Denmark offer hospitals in the Nordic countries

Scandiatransplant is an organisation which administers exchange of organs for transplantation in Denmark, Finland, Iceland, Norway and Sweden. The organisation covers approx. 25 mio. citizens and is owned by the ten Nordic hospitals performing organ transplantations in the countries mentioned. The number of inhabitants in the individual country is too small to ensure an optimal matching of organ from donor with the best recipient of the organ and to maintain a reliable and efficient urgent waiting list.

This legal memorandum describes the structure enabling exchange of personal information among the involved hospitals with the purpose of coordinating the activities within organ transplantation.

The structure is outlined in appendix 1¹. The description below is based on the instructions and data flows described in the appendix.

The purpose of the structure is to ensure an efficient transparent safe medically and ethically correct allocation of organs for transplantation that could not have been effected through the hospitals' manual communication with each other by telephone, ordinary mail or e-mail. To solve the administrative work of finding patients and organs that match, Scandiatransplant acts as a common office for the members of the association and performs the communication function which the hospitals would otherwise have to perform individually.

¹To simplify the graphical presentation of instructions and data flows in appendix 1, only two hospitals are applied in it (called A and B). These represent members of Scandiatransplant placed in different Nordic countries and therefore comprised by different national regulation.
Determination of the data control
The different parties' roles are briefly described below. The purpose is to form basis of the superior description of the data flows enabling the hospitals to exchange the organs by applying a common IT-system.

Data controllers: The ten hospitals
The ten Nordic hospitals are the data controllers\(^2\) for own data and they entrust Scandiatransplant with these data, and Scandiatransplant acts as data processor on behalf of the ten hospitals. The individual hospitals are liable for observing local legislation.

In appendix 1 (for the sake of clarity) the hospitals have been reduced to two units: A and B. The principles for entrusting an other party with data and application of data are the same however, regardless of two or ten data controllers.

Data processor: Scandiatransplant
Scandiatransplant is an association with Central Business Register number: 16061891 and is thus an independent legal unity placed outside direct control of the hospitals.

Scandiatransplant acts as data processor\(^3\) on behalf of its members in connection with solving the limited role as provider of organs for transplantation. The association receives instructions from the ten hospitals which pay Scandiatransplant to perform the tasks of the association, and which in addition take part in the management - for example by nominating members for the council of representatives of the association.

Subsupplier: Region Central Denmark
Region Central Denmark is Scandiatransplant's subsupplier in server maintenance. As subsupplier Region Central Denmark ensures to act in accordance with the instructions that Scandiatransplant receives from the data controller hospitals. As the Region maintains the servers on a daily basis, the Region is responsible for the superior IT-security connected to these servers.

Scandiatransplant pays Region Central Denmark an amount to assist the association in managing certain HR-functions, a.o. payment of salaries to the employees. To make the Region's management as flexible as possible, the association has voluntarily chosen to observe the public legal regulation and the politics and guidelines which the Region must observe.

Finally, Region Central Denmark provides rooms for the work of the association.

Instructions and data flows
To ensure data processing connected to the management of Scandiatransplant, it is necessary that the members of the association entrust the association with an amount of personal information

\(^2\) cf. personal data act § 3, No 4.
\(^3\) cf. personal data act § 3, No 5.
Prior to entrusting the association with the personal information, the data controller hospitals have made data processor agreements\(^4\) with Scandiatransplant and ensured that the association operates in correspondence with these instructions.

The appropriate instructions and data flows are summarized in this way\(^5\):

1. The hospitals' instructions to Scandiatransplant
2. Scandiatransplant's way of operation
3. Scandiatransplant's instructions to Region Central Denmark
4. The Region as subsupplier
5. The follow-up database
6. The database on patients and donors.
7. The possibility of the data controller to get access to own data about registered patients
8. The possibility of the data controller to get access to other parties' information concerning organs
9. Scandiatransplant's possibility to apply personal information from the databases for quality development and research.

Below the individual data processes and instructions are described.

**1. The hospitals' instructions to Scandiatransplant**

According to the personal data directive's paragraph 16 the data processor may solely work according to the data controller's instruction. In practice the instruction allowance is implemented through participation in the council of representatives of the association where all members of Scandiatransplant are represented.

The council of representatives has the superior responsibility to ensure that Scandiatransplant processes data in a way that observes all members' national regulation and the instructions which the council of representatives present to the association. In practice this happens through negotiation which includes a certain standardisation of the members' instructions, but there is constantly focus on the personal data directive's paragraph 17, subsection 1, according to this the data controllers are all obliged to take necessary technical and organisational measures to protect personal information against accidental or illegal destruction, against accidental loss, against deterioration, unauthorized publication or non-authorised access.

**2. Scandiatransplant's way of operation**

It appears from the personal data directive's paragraph 17 subsection 3 that a written agreement must be made when data controller applies data processor.

Therefore data processor agreements have been made between Scandiatransplant's members and the association which describe the cooperation and the obligations that the association has in connection with the entrusted data which the association keeps and processes on behalf of the members.

\(^4\) cf. personal data act § 42, subsection 2.

\(^5\) The listing applies same numbering as appendix 1.
3. Scandiatransplant's instructions to Region Central Denmark
The Region works within the regulation that regulates public authorities’ handling of personal information, and within this regulation, the Region observes the instructions which the board of the association presents to the Region as subsupplier.

4. The Region as subsupplier
The Region acts as Scandiatransplant's subsupplier and thus performs the tasks on behalf of the association in correspondence with the existing agreement between Scandiatransplant and Region Central Denmark.

5. The follow-up database
This database contains names, Civil Registration System numbers and the like connected to the registered patients and donors and are directly applicable to identify these.

As the figure in appendix 1 illustrates, only the hospital which has supplied these data to the database has access to data.

In this situation Scandiatransplant functions as a data warehouse which stores the data of the members of the association and delivers them to the data controller when required.

6. The database on patients and donors
"The core database" contains information connected to the organs which the individual hospitals are able to exchange.

On basis of the instructions which the association has presented to Scandiatransplant, the association has developed an IT-system which the members of the association apply. A hospital which has an organ can enter information about the organ into the system which hereafter renders proposals of a recipient at one of the hospitals connected to the system. Hereafter the receiving hospital is contacted which can get access to the database and find information about the organ it wants to receive.

7. The possibility of the data controller getting access to own data about registered patients
To ensure the validity of the entered data, the hospitals have always the possibility to see own entered data and correct these. This also appears from the described structure where Region Central Denmark solely is subsupplier of Scandiatransplant.

8. The possibility of the data controller getting access to other parties' information connected to patients and donors.
The purpose of "the core database" is that the receiving hospital is able to get access to information about organs which the hospital will receive.

This access to other data controllers’ data takes place when Scandiatransplant's IT-system proposes a patient as recipient. Hereafter the receiving hospital is contacted according to the instructions which Scandiatransplant has received from the members of the association. The receiving hospital can now get access to the data of the donor.
9. Scandiatransplant's possibility to apply or pass on personal information from the databases for quality development and research
If Scandiatransplant has received instruction from the members of the association to make quality assurance or pass on personal information to research projects, the association can perform this function on behalf of the data controller.
In connection with passing on data, Scandiatransplant ensures that the national legislation of the members is observed especially within health legislation and personal data legislation.
Appendix A: Ten different data controllers