



NAME:

MEDICAL RECORD No.:

DATE: / /

SEX:

INFORMED CONSENT
IDENTIFIER: I-TRC-001
Version: 2.1 - 25 January 2021



EUROPEAN REFERENCE NETWORK ON
TRANSPLANTATION IN CHILDREN
ERN TRANSPLANTCHILD

PROCEDURE: ACCESS TO EUROPEAN REFERENCE NETWORKS AND INCLUSION IN THE PAEDIATRIC TRANSPLANT EUROPEAN REGISTER (PETER)

DATA SHARE IN EUROPEAN REFERENCE NETWORKS

Description of the European Rare Disease Reference Networks

- **What it consists of:** The European Reference Networks (ERNs) are networks of healthcare professionals across Europe working for rare diseases. They are established by Directive 2011/24/EU and exist to allow collaboration between healthcare professionals to assist patients with rare diseases and other conditions requiring very special therapeutic procedures.
- **How it is done:** With your consent and in accordance with national and European data protection laws, your case may be transmitted to the above-mentioned ERNs so that healthcare professionals in the ERNs can assist your doctor in determining your diagnosis and treatment plan. To do this, the data collected of you in this hospital must be able to be shared with healthcare professionals in other hospitals, some of which may be located in other European countries. The data shall not include your name or address but shall instead include medical images, laboratory reports, as well as biological sample data. Letters and reports from other doctors who treated you in the past could also be included.
In any case, your treatment will continue to be carried out by the healthcare professionals who were already treating you and your data will not be shared with third parties without your consent. If you decide not to share your data, your doctors will continue to treat you as best they usually do.
- **How long it lasts:** Until you change your mind and decide to revoke this consent. Your doctor will explain how you can delete your data from the records if you wish to do so. You may not be able to delete the information that has already been used for your treatment.

INCLUSION IN REGISTRIES AND RESEARCH PROJECTS

Inclusion in databases/registers of rare diseases:

In order to improve knowledge about rare diseases, ERNs rely heavily on information databases for research and knowledge development. Databases, also called records, contain only pseudonymised information. Your name and address will NOT be included; only information about your illness will be included.

To help build databases, you can give your consent to include your data in this type of database. If you decide not to give your consent, this will not affect your treatment.

Participation in research projects on rare diseases:

You can also tell us if you want registry staff and or investigators to contact you to inform you about research projects for which your data could be used. If you decide to share your research data, they will contact you to get your consent for a specific research project. Your data will not be used for research if you have not given your specific consent for a particular research project.

WHAT ARE MY RIGHTS?

- You have the right to decide whether or not to give your consent to share your data with the ERNs. If you decide to give your consent today, you can change your mind at any time.
- You have the right to receive information about the purposes for which your data will be used and who will have access to it. Your doctor will tell you about it if you need more information.
- You have the right to see what data has been stored about you and also to make corrections in case you notice errors. You may also have the right to block or delete your data.
- The hospital that has collected your data is responsible for your data and has a duty to ensure that your data is processed securely and to inform you if a data security breach has occurred.
- If you have any concerns about how your data has been processed, you should contact your doctor or relevant national data protection authorities.
- Your hospital will review the need to keep your data on ERNs every 15 years.

WHAT OTHER ALTERNATIVES ARE THERE?

Sharing your data through the European Reference Networks is voluntary, as are inclusion in registries and participation in research projects. If you decide not to give your consent, we remind you that this will not affect the care you are receiving at the hospital.

DO YOU AUTHORIZE US?

For this document we request the authorisation to share your data within the ERNs(s) and to include you in the European Register on Paediatric Transplantation promoted by the European Reference Network on Transplantation in Children.

DECLARATIONS AND SIGNATURES

Before signing this document, if you need more information or have any questions about your health care, do not hesitate to ask us. We will gladly attend you. We inform you that you have the right to revoke your decision and withdraw your consent at any time.

1. Concerning relatives and guardians:

Patient Mr./Mrs. has no capacity to decide at the time of signature. I, Mr./Mrs..... with national ID....., declare to have been sufficiently informed of the procedure to be performed. Therefore, I expressly give my consent. My acceptance is voluntary and I understand that I can withdraw this consent. I GIVE MY CONSENT TO:

YES NO

That the pseudonymised patient data can be shared in the ERNs for my TREATMENT.

I understand that my data will be shared with healthcare professionals in the ERNs so that they can work together to assist on my treatment. My acceptance is voluntary and I can withdraw this consent when I think it is opportune, without this decision having an impact on my subsequent care.

That pseudonymised patient data are included in the PETER registry (Paediatric Transplant European Registry) or in other ERNs databases.

I would like **to be briefed on research projects**. I will decide whether I consent to the use of patient data in a specific project when I am contacted.

Parent/Guardians' signature

Date:/...../.....

2. Concerning the doctor:

Dr. has informed the patient or guardian of the nature of the procedure to be performed, including risks, complications and other possible alternatives.

Doctors' signature

Date:/...../.....

3. Concerning the patient:

I, Mr./Mrs.....with national ID , declare to have been sufficiently informed of the meaning of having my data being shared in the ERNs, including my data in records and the possibility to participate in research projects.

Patients' signature

Date:/...../.....

4. Concerning the NON-ACCEPTANCE of Informed Consent:

I, Mr./Mrs.....with national ID , have been informed that I can revoke this document /at any time, so I declare that I do NOT give my Consent to submit /my health data to the registry, leaving my previous Consent null and void. I wish to make the following observations

.....
.....

Patients' signature

Date:/...../.....

VOLUNTARY PARTICIPATION

You should be aware that your participation is voluntary and that you may decide not to participate or change your decision and withdraw your consent at any time, without this altering the relationship with your doctor or causing any disturbance to your treatment.

ECONOMIC COMPENSATION

Your participation in the study will not entail any additional expense or financial compensation.

CONFIDENTIALITY AND PERSONAL DATA PROTECTION POLICY

As of 25 May 2018, new legislation on personal data in the EU, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (GDPR), is fully implemented. It is therefore important to know the following information:

Your personal data will be processed for the purpose indicated in the document subject to signature and will be kept for the years necessary to comply with the applicable regulations. The Controller is the Hospital Universitario La Paz (including Hospital Carlos III-Hospital Cantoblanco), whose Data Protection Delegate (DPD) is the “DPD Committee of the Department of Health of the Community of Madrid” with direction at C/Melchor Fernández Almagro nº 1-28029 Madrid;protecciondedatos.sanidad@madrid.org. The legal basis for treatment is its consent (Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use and repealing Directive 2001/20/EC; Law 14/2007 of 3 July on biomedical research; Royal Legislative Decree 1/2015, of 24 July, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices; Law 44/Law 44/2003 of 21 November on the organisation of the health professions, as well as Law 14/1986 of 25 April, General of Health, Law 41/2002 of 14 November on patient autonomy, and other legislation in force in the field of health).

Your data will not be transferred, except in cases required by law or in cases of medical emergency. However, at any time you may revoke the consent given, as well as exercise your rights of access, rectification, suppression, opposition, limitation of treatment and portability, to the extent that they are applicable, through written communication to the Head of the Treatment (Principal Investigator of the study), domiciled at Pº de la Castellana, 261, 28046 Madrid, specifying your request, together with your ID or equivalent document. We also inform you of the possibility to file a complaint with the Spanish Data Protection Agency (C/Jorge Juan, 6 Madrid 28001) www.agpd.es

Access to your personal information shall be restricted to the study physician/collaborators, health inspection authorities, the Ethics Committee for Clinical Research, when required to verify the study data and procedures, but always maintaining confidentiality.

The data collected for the study will be identified by code, so that information that can identify you is not included, and only your study doctor/collaborators can relate the data to you and your medical history.

On the basis of such data, scientific communications may be prepared to be presented to scientific conferences or journals, always maintaining the confidentiality of your personal data at all times.

CONTACT DETAILS

If you have any questions in the future about the disclosure or use of your medical data, if you have doubts, concerns, or complaints about or your participation in the study, you should contact:

Dr. Paloma Jara Vega, or the technical secretariat of ERN TransplantChild, at the Fundación para la Investigación Biomédica – Hospital La Paz – FIBHULP, at phone number +34 91 727 75 76

More information about ERNs can be found at https://ec.europa.eu/health/ern_es