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|  | **NAME:** ..................................................................  **NHC:** .......................... **DATE: / / GENDER:** ......... |
| INFORMED CONSENT IDENTIFICATION: EC approval  Version: version and date | **EUROPEAN CHILD TRANSPLANT REFERENCE NETWORK**  ERN TRANSPLANTCHILD |
| PROCEDURE: ACCESS TO EUROPEAN REFERENCE NETWORKS AND INCLUSION IN THE EUROPEAN PEDIATRIC TRANSPLANT REGISTRATION (PETER) | |
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| Sharing data on European Reference Networks | |
| Description of the European Reference Networks for Rare Diseases   * **What it consists of:** The European Reference Networks (ERNs) are networks of health professionals across Europe working on rare diseases. They are established by Directive 2011/24/EU and exist to enable collaboration between healthcare professionals to help 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 forwarded to the ERN(s) mentioned above so that the healthcare professionals of that ERN can help your doctor determine your diagnosis and treatment plan. To do this, the data collected about you in this hospital must be able to be shared with healthcare professionals from other hospitals, some of which may be located in other European countries. The data will not include your name or address but, instead, medical images, laboratory reports, as well as data from biological samples. Letters and reports from other doctors who have treated you in the past may also be included.   In any case, your treatment will continue to be carried out by the health professionals who were already treating you and your data will not be shared with third parties without your consent. If you choose not to share your data, your doctors will continue to treat you as well as possible   * **How long it lasts:** Until you change your mind and decide to revoke your consent. Your doctor will explain how you can delete your data from the records if you wish. Information that has already been used for processing may not be deleted | |
| Inclusion in registers and research projects | |
| Inclusion in rare disease databases/registers:  In order to improve knowledge on rare diseases, ERNs rely heavily on information databases for research and knowledge development. Databases, also called registers, only contain pseudonymised information. Your name and address will NOT be included; only information about your disease will be included.  To help build the databases, you can give your consent to include your data in these types of databases. If you choose not to give your consent, this will not affect your treatment in any way.  Participation in research projects in rare diseases:  You can also tell us if you want to be contacted about research projects for which your data may be used. If you decide to share your data for research, you will be contacted to give 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 ERN(s). 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 can tell you about this if you want 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 there has been a security breach in it. * If you have any concerns about how your data has been processed, you can contact your doctor or the relevant national data protection authorities. * Your hospital will review the need to keep your data in the ERN(s) every 15 years. | |

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| WHAT OTHER ALTERNATIVES ARE THERE? |
| Sharing your data through the European Reference Networks is voluntary, as is inclusion in registers and participation in research projects. If you choose not to consent, we remind you that this will not in any way affect the care you are receiving at the hospital. |
| Do you authorize us? |
| For this document we request the authorization to share your data within the ERN(s) and include you in the European Registry in Pediatric Transplantation promoted by the European Reference Network in Child Transplantation. |
| Declarations and signatures |
| Before signing this document, if you want more information or have any questions about your health care, do not hesitate to ask us. We will gladly assist you. We inform you that you have the right to revoke your decision and withdraw your consent, at any time.   1. Relating to family members and guardians:   Patient D./D.a does not have the capacity to decide at this time.  D./D.a .............................................................................. with D.N.I and in quality  from I have been sufficiently informed of the procedure to be carried out.  Therefore, I expressly give my consent. My acceptance is voluntary and I can withdraw this consent when I see fit. I GIVE MY CONSENT TO:  YES NO   Pseudonymised **patient data to be shared in the ERN(s) for my TREATMENT .** I understand that my data will be shared with healthcare professionals in the ERN so that they can work together on my treatment. My acceptance is voluntary and I can withdraw this consent when I deem it appropriate, without this decision affecting my subsequent care.   Pseudonymised **patient data to be included in the PETER** (PaEdiatric Transplant European Registry) **or other ERN databases**   I would like **to be informed about research projects.** I will decide whether I consent to the use of patient data in a specific project when they contact me.  Signature of guardian or family member Date: .........................................................................................................................................................   1. Concerning the doctor:   Dr./Dr. I have informed the patient and/or the guardian or family member of the  object and nature of the procedure to be performed explaining the risks, complications and possible alternatives.  Signature of the doctor Date: .......... / ............../ ...............   1. Relating to the patient aged 12 to 17 years (Assent):   Mr/Ms ..............................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................  I have been sufficiently informed of what it means to share my data in ERNs, to include my data in registries, and to be able to participate in research projects.  Patient's signature Date: .........................................................................................................................................................   1. Regarding the non-acceptance (REVOCATION) of the Informed Consent:   Mr/Ms ..............................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................  I have been informed that I can revoke this document prior to the completion of the procedure, so I declare that I **do NOT** give my Consent to submit to the realization of the same, leaving without effect my previous Consent. I wish to make the following remarks ..................................................................................................................................................................................................................................................................................  ..........................................................................................................................................................................................  Patient's signature Date: .......... / ............../ ............... |

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| Voluntary Participation |
| You should know that your participation is voluntary and that you can decide not to participate or change your decision and withdraw consent at any time, without altering the relationship with your doctor or causing any harm in your treatment. |
| Economic Compensation |
| Your participation in the study will not entail any additional costs or financial compensation. |
| Confidentiality / Protection of personal data |
| As of May 25, 2018, the new legislation on personal data is fully applicable in the EU, specifically Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD). Therefore, it is important that you know the following information:  Your personal data will be processed for the purpose indicated in the document to be signed and will be kept for the years necessary to comply with current applicable regulations. The Data Controller is Hospital Universitario La Paz (including Hospital Carlos III-Hospital Cantoblanco), whose Data Protection Officer (DPD) is the ‘DPD Committee of the Ministry of Health of the Community of Madrid’ with address at C/ Melchor Fernández Almagro No 1 - 28029 Madrid; [protecciondedatos.sanidad@madrid.org.](mailto:protecciondedatos.sanidad@madrid.org) The legal basis for the processing is your consent (Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC; Law 14/2007 of 3 July 2007 on biomedical research; Royal Legislative Decree 1/2015 of 24 July 2015 approving the recast text of the Law on guarantees and rational use of medicines 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 Health Law, Law 41/2002, of 14 November, on patient autonomy, and other legislation in force in health matters).  Your data will not be transferred, except in cases required by law or in cases of medical urgency. However, at any time you can revoke the consent given, as well as exercise your rights of access, rectification, deletion, opposition, limitation of treatment and portability, to the extent that they are applicable, through written communication to the Data Controller (Principal Investigator of the study), with address at Po de la Castellana, 261, 28046 Madrid, specifying your request, along with your ID or equivalent document. We also inform you of the possibility of filing a claim with the Spanish Data Protection Agency (C/Jorge Juan, 6 Madrid 28001) [www.agpd.es](http://www.agpd.es/)  Access to your personal information will be restricted to the study doctor / collaborators, health authorities in matters of inspection, the Clinical Research Ethics Committee, when they need it to verify the data and procedures of the study, but always maintaining the confidentiality of them.  The data collected for the study will be identified by a code, so that no information is included that can identify you, and only your study doctor/collaborators will be able to relate such data to you and your medical history.  From these data, scientific communications can be prepared to be presented to congresses or scientific 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 that may be made of your medical data, if you have questions, concerns or complaints about the study or your participation in it, you should contact:  Dr/Dra Francisco Hernández Oliveros, or the technical secretariat of ERN TransplantChild, at the Foundation for Biomedical Research – Hospital La Paz – FIBHULP, phone 91 727 75 76  More information on ERNs is available at https://ec.europa.eu/health/ern\_en |