ERN CRANIO Registry

PATIENT INFORMED CONSENT FORM

Dear parent(s)/legal representative,

We invite your child/the patient[1] to take part in a patient registry for rare and/or complex craniofacial anomalies and ear, nose and throat (ENT) disorders . Participation is voluntary and requires your written consent as a legal basis to use the data of your child/the patient. Please read this information carefully and ask the medical doctor of your child/the patient for an explanation if you have any questions.

EUROPEAN REFERENCE NETWORK REGISTRIES

- European Reference Networks (ERNs) are networks of expert healthcare professionals for rare diseases from specialised healthcare providers across Europe. ERN CRANIO is the ERN for rare and/or complex craniofacial anomalies and ear, nose and throat (ENT) disorders. Specifically, ERN CRANIO is focused on cleft lip/palate, craniosynostosis, ENT disorders, orodental anomalies, and other rare/complex craniofacial conditions.
- The diseases included in ERN CRANIO are rare and the number of patients is often limited. Therefore, ERN CRANIO aims to combine the disease-specific expertise, knowledge, and resources from across Europe. Bringing together knowledge from a large number of health care providers will allow us to achieve goals that would be unachievable in a single country. More detailed information on ERN CRANIO can be found by scanning the QR-code on the right.
- To understand the course of a disease and investigate diagnostic procedures and treatments, we need a database (also known as a registry) to store collected information for research. This registry will be used to compare (long-term) results from a large number of patients from different countries and different health care providers. Based on these results we aim to identify the best treatment and follow-up protocols to optimise and standardise health care for patients with rare craniofacial and ENT disorders across Europe.
- Only the data required for such research will be recorded and may be shared with users as outlined below. Such data may include age, sex, the signs and symptoms of the disease, results of diagnostic procedures (e.g., laboratory test results, genetic information, imaging studies), as well as therapeutic interventions (e.g. surgery) and their (long-term) outcomes.
- We ask for your consent to include the data of your child/the patient in the ERN CRANIO registry for research. Data is pseudonymized and is stored in accordance with national and European data protection laws and ethics guidelines. Details are described below.
- Your child/the patient's data privacy will be secured as described below in this form. Only the healthcare providers of your child/the patient will be able to link your child/the patient to your child/the patient. Therefore, the risk of re-identification by unauthorized persons is minimal.

VALUE & BENEFITS

[1] Adult for whom you are legal guardian

HOW WILL THE DATA BE USED?

The data collected in this registry is used to improve the delivery of healthcare, including the diagnosis, treatment and prognosis of patients with rare and/or complex craniofacial anomalies and ear, nose and throat (ENT) disorders.

Only users authorised by the **ERN CRANIO Scientific Committee** can use the data. This Committee is composed of qualified health professionals and patients' representatives from the ERN CRANIO member hospitals. The Scientific Committee ensures requests to access the registry data are in line with the procedures described in the data access policies.

The Scientific Committee may provide data access to **clinical researchers from within ERN CRANIO,** to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases**.** Also, registry data will be made public via annual reports and may be shared with **health authorities, policy makers and regulators** to inform their decisions on rare disease health policy and approval of medicines. The data will not be used for commercial purposes.

Data transfers outside the EU

Data without any personally identifiable information may also be provided to researchers working in countries outside the EU, where the General Data Protection Regulation (GDPR) does not apply. In this case, a written agreement will be set up to ensure that the data is processed in compliance with the GDPR. You may choose if you want to allow the transfer of the data of your child/the patient to non-EU countries to contribute to projects directly aligned with the aims of this registry within a framework compliant with GDPR.

Re-contacting to participate in research projects

In the future, research projects on the diseases and conditions covered by this registry may be proposed. You may choose if you want to be re-contacted by the medical doctor of your child/the patient to participate in such studies. If you agree to be contacted, you are free to refuse, without any prejudice, participation in the proposed studies after you have been fully informed. The current care of your child/the patient will not change in any way if you choose not to give your consent.

WHAT ARE THE BENEFITS?

While there is no direct benefit from participating in this registry, the knowledge about the disease will be improved. This may benefit your child/the patient and other patients suffering from the same disease.

The participants may benefit by facilitated access to clinical studies aimed to prevent and treat the disease.

Communication of research results

The results of the research will be communicated through the registry website and publication in scientific journals. Data will be pseudonymized (coded) and shared in aggregated form to ensure your privacy is guaranteed. The privacy of the data your child/the patient's data will always be protected as described below.

PROTECTION

WHAT ARE THE RIGHTS OF THE REGISTRY PARTICIPANT?

- You decide whether to let your child/the patient participate in the registry. Please take as much time as you need to make this decision. You do not have to sign anything. You can decline participation without giving any reasons. Your child/the patient will receive the same treatment irrespective of whether or not you agree to participate in this registry.
- You have the right to give or withhold your consent at any time. If you consent today, you may modify or withdraw your consent later, without any prejudice. The medical doctor of your child/the patient will explain how your consent can be modified and how the data can be removed from the registry if you wish so. Please be informed that, to guarantee the validity of any research performed, data already

processed cannot be deleted. However, this data will not be used in new research projects after withdrawal.

- You are entitled to receive further information about the purposes for which the data of your child/the patient will be processed and who will have access to it. You can also request to access the data of your child/the patient at any time.
- The hospital where your child/the patient is treated is the "data controller" responsible for the **local protection** of confidential patient data. If you have any concerns about the way in which the data of your child/the patient is processed, you would like more information or to exercise your rights, you may contact the Data Protection Officer, or you may raise a complaint to the relevant data protection authority. You can contact details of the local Data Protection Officers through: [NAME] [email address of DPO]
- For all data submitted to the **central registry database**, the Erasmus MC, Rotterdam, the Netherlands, coordinating centre of the ERN CRANIO network, is responsible for the protection of the data, its storage, use and access.
- When your child reaches legal majority, the hospital will approach your child again to check whether he/she wishes to stay in the registry.

HOW WILL DATA BE SECURED?

- Participation in the registry will be kept strictly confidential and all information will be handled through secure electronic systems. The system is password protected and only persons specifically involved with the registry will have access.
- The registry users and administrators will not be able to contact you because the name of your child/the patient, address and hospital number will not be recorded. All your child/the patient's data will be pseudonymised before being stored in the registry. This means that all identifiers that relate to your child/the patient will be removed and replaced by a pseudonym[2]. Only the medical doctor of your child/the patient can link the pseudonym to your child/the patient. Therefore, the risk of re-identification by unauthorized persons is minimal.
- In all publications emerging from the registry, it will be ensured that it is not possible to identify an individual patient, e.g., by providing data in tables or presenting age categories rather than the real age (aggregated data).
- A pseudonymisation service will be used for this purpose. It allows to identify duplicate registration of patients, linkage between registries and other data resources, keep data protected and preserve the possibility of re-contacting by the medical doctor in charge.
- The registry data will be stored on a secure server in Europe. The data will be kept in the database for a maximum of 50 years. After this, your data will be destroyed.

COULD PARTICIPATION IN THE REGISTRY CAUSE ANY HARMS?

- Participating in this observational registry will not cause any health risks.
- Even though the registry has processes in place to ensure your child/the patient's personal information is protected, there is a remote risk the data could be matched with information you have already authorized in publicly available databases such as ancestry websites or public rare disease registries with identifiable information. To minimize this risk, researchers asking for access to registry data will confirm in writing not to try to identify you by any means, applying their duty of professional secret.

ADDITIONAL INFORMATION

[2] A pseudonym is a sequence of letters and numbers that replaces all identifiers that relate to a patient; the data of the patient is then called "pseudonymised data". These identifiers can only be retrieved, from the pseudonym, by the authorised health care professionals enrolling the patient in the registry.

Costs

Participation in this registry will not entail any costs for your child/the patient.

Ethics Committee Approval

This Informed Consent Form has been reviewed and approved under the number <Ethics Committee/ IRB number> by [name of the (local) Ethics Committee/IRB

If you have any other question about the registry, please contact:
[Name Local Principal Investigator]
[Contact details local PI]

INFORMED CONSENT

Patient First and Last Name:……

Date of Birth (dd/mm/yyyy): ... ... / ... .. / .. .. ID number:……

☐ I am the parent ☐ I am the legal representative[3]

Parent/ Legal Representative First and Last Name: ……

- I have read the information sheet about the ERN CRANIO registry.
- I have been given the time and opportunity to ask questions about the objectives of the registry and the use of the data of my child/the patient and that I have solved all my doubts with the medical doctor.
- I understand that the participation of my child/the patient is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting the future medical care of my child/the patient.
- I approve that the data of my child/the patient will be stored in the ERN CRANIO registry, used for non-profit purposes and shared with approved users to improve the delivery of healthcare as described above.
- I consent to the processing of my child/the patient pseudonymized data for the purposes described above.

The following consent conditions are optional. Please indicate your preferences by writing your initials in the relevant box. If you leave the boxes empty, we assume you agree to the statements.

YES	NO	
		I CONSENT that the pseudonymized data of my child/the patient **may be transferred to non-EU countries, in compliance with GDPR, to** support projects aimed to improve healthcare.

Optional, at ERN discretion

[3] *Patients not able to consent by their own (age or legally incompetent or mentally incompetent) must be also involved in the process of information to the extent permitted by their comprehension grade and maturity. The age to which the capacity of consent for processing of data is recognized, varies according to the national legislations. Once minors reach the legal age of maturity, they will be asked to provide their consent to continue participating in the registry. The need to ask for consent to all persons holding the parental responsibility of the patient depends on the national regulations. People holding the parental responsibility of the patient, shall sign this consent in different (duplicated) documents.*

☐	☐	**I CONSENT** that the pseudonymized data of my child/the patient may be **linked to existing databases/registries** to improve healthcare.
☐	☐	**I WOULD LIKE TO BE CONTACTED** by the medical doctor of my child/the patient about any **research project and/or clinical study related to my child/the patient's condition.**
☐	☐	**I WOULD LIKE TO BE INFORMED** by the medical doctor of my child/the patient **about any incidental finding** that is directly relevant to my personal health or to the health of my family members.

PARENTS/LEGAL REPRESENTATIVE	MEDICAL DOCTOR / AUTHORISED WITNESS
	Full name: Position:
Date and Signature:	Date and Signature:

Please keep one copy of this Informed Consent Form in case records and hand one copy to the person who has signed this form.