The Core Registry: a European Registry for Rare

endocrine and bone disorders

Dear parent(s) and/or caregiver(s),

This letter provides you with information about the Core Registry for rare endocrine and bone conditions, which our department participates in. We ask for your permission to share your child’s data with this Core Registry. Participation is voluntary, but we need your written consent.

Before you decide, we will explain what the registry is about. Please take your time to read this information carefully and ask your doctor or specialist nurse if you have any questions.

**Why was this Core Registry set up?**

The European Union has set up networks for rare conditions. Two of these are the European Reference Network (ERN) for rare endocrine conditions (Endo-ERN) and the European Reference Network for rare bone conditions (ERN BOND) ([www.endo-ern.eu](http://www.endo-ern.eu) and [www.ernbond.eu](http://www.ernbond.eu)). These networks aim to gather as much information as possible about the rare conditions by setting up a registry: EuRREB (European Registries for Rare Endocrine and Bone conditions - [www.eurreb.eu](http://www.eurreb.eu)).

**What is the purpose of a registry?**

Registries are used by doctors, patients, and researchers to learn more about rare conditions or to find out what the best treatment is. Registries can help improve our knowledge of these rare conditions and the care of people with them. Registries can connect care and research.

The Core Registry collects important information about these endocrine and bone conditions. This information is also collected by the doctor as part of "normal" care (e.g. height or what medications your child is taking) and is included in the medical record.

**We currently register the following conditions:**

* Adrenal disorders
* Bone disorders
* Calcium & Phosphate Homeostasis disorders
* Genetic Disorders of Glucose & Insulin Homeostasis
* Genetic Endocrine Tumour Syndromes
* Growth & Genetic Obesity Syndromes
* Hypothalamic and Pituitary conditions
* Sex Development & Maturation disorders
* Systemic and Rheumatological disorders
* Thyroid disorders

For some conditions, more information is collected in a condition specific module. For an overview of all condition specific modules: <https://eurreb.eu/condition-specific-modules/> please visit our website.

**What does it mean to participate?**

You and your child do not need to do anything extra. No additional tests are required. Data from your child’s medical file is transferred to a secure website. No one can see your personal data, such as your name or address, except the treatment team.

**You can create your own account to view data.**

If you agree that the data will be safely included in the registry, you can choose to create an account yourself. As a patient, you can see what information is collected, but you need access. If you would like access, your email address (provided on this form) will be shared with the project team, so that you can create an account. You can find more information about the data collection and the registry at [www.eurreb.eu](http://www.eurreb.eu) (section Patient Information).

You and your child also have the opportunity to contribute to the data collection by answering a number of questionnaires. These are about, for example, quality of life and patient satisfaction with care.

Creating an account or filling out questionnaires is not mandatory.

The registry will never contact you directly, even if you create an account. However, you may receive general reminders if questionnaires are left incomplete. The healthcare team may also send reminders through the system.

**Sharing and publishing of research results**

Data from the registry may be used for scientific research. Only anonymized data can be used, and only after approval by a special committee that includes patient representatives. The results will be published in scientific journals, the Registry's website, the European Reference Network or on the Registry's social media.

Readers of these publications will not know your child participated in the study.

The registry collaborates with:

* Other (inter)national registeries;
* European Reference Networks for Rare Diseases (ERN’s);
* Researchers from scientific/clinical/patient organizations.

**Data storage**

The registry is designed to study long-term outcomes. Therefore, data is stored for as long as the registry exists, and for 10 years after it ends stored. This is necessary because there are very few patients with the same rare condition as your child. You and your child can always choose to stop the data collection at any time.

**What are the possible risks or downsides of the Core Registry?**

We see no disadvantages to participating.

**If you do not want to participate or want to stop**

If you indicate on the attached form that you do not wish to participate, your child’s information will not be stored or shared. This will not affect your child’s treatment.

If you do participate, you can change your mind at any time without giving a reason. Notify your healthcare team or make changes directly on the website. Per your request all the data of your child can be removed from the registries and not used for future research, however, data that has already been shared with researchers is allowed to be used within their research.

**End of the registry**

Participation in the registry ends if:

* You or your child decide to stop;
* EuRREB, the regulatory authorities or the ethics committee decides to end the registry.

**Sharing data outside the European Union (EU)**

For scientific research, non-traceable data about your child from the registry can also be forwarded to researchers in countries outside the EU. These countries may not have the same privacy rules as the EU. However, the registry will ensure that contracts are in place requiring these researchers to protect your child’s data to the same standard as within the EU.

**More information about data rights**

For more information on your rights in data processing, please consult your countries Data Protection Authority’s website.

**1. Inform**

A note will be made in your child's file that you are participating in the Core Registry. No one else will be informed about this.

**2. No Fee for participating**

You or your child will not be paid for participating in the registry.

**3. Questions?**

For questions or more information, please contact: [registries@lumc.nl](mailto:registries@lumc.nl).

**4. Sign the consent form**

After considering, you will be asked to decide if you want to participate in this registry. If you want to give your permission, please sign the consent form. Both you and your doctor will receive a signed copy.

Thank you for your attention and cooperation, on behalf of all doctors contributing to the Core Registry.

EuRREB Management Team

**Consent Form for sharing data with the Core Registry**

I have read the information letter and I have had the opportunity to ask questions. My questions have been fully answered. I had enough time to decide whether I want my child to participate and I know that joining is voluntary. I also understand that I can choose to stop my child’s participation at any time without giving a reason.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| With this consent form, I give permission for: |  |  | | |
|  | **YES** | **NO** | | |
| 1. Data collection of my child's data in the Core Registry. The data can be kept for as long as the registry exists, and 10 years after it ends. |  |  | | |
| 1. I would like access to this data. Access codes can be sent to the following email address:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | ☐ | | |
| 1. I consent to my child's personal data being shared in the Core Registry with third parties as described above. The condition is that my child’s privacy is protected with a sufficient level of security or contractual precautions are taken if the data is transferred outside the EU. |  |  | | |
| 1. I give permission to contact my child to fill in questionnaires. |  | |  |
| 1. I would like to receive the newsletters of the registry. |  | | ☐ |
| 1. I give permission to record information about any gene mutations related to my child's condition in the registry. |  | |  |

**Your child's name (<16 years):**

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**Name parent and/or caregiver 1 (first and last name):**

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**Name parent and/or caregiver 2 (first and last name):**

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**Name of doctor or nurse practitioner (or his/her representative):**

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*The organization of this registry will carefully monitor the rules that currently apply to registration, even if, for example, government laws change. If the rules for this registry have to change in the future, we will inform you if necessary. You may be asked to provide consent again to continue participating.*