The Core Registry: a European Registry for rare

endocrine and bone conditions

Dear Sir/Madam,

We would like to ask you to share your data with the Core Registry. Participation is voluntary. However, we do need your written permission to participate.

Before deciding whether you want to participate, you will receive an explanation of what the registry is. Please read this information carefully and ask your doctor or specialist nurse if you have any questions. You can also talk about it with your partner, friends, or family.

**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 about these conditions and the care of people with them. Registries can connect care and research.

The Core Registry collects important information about your condition(s). This information is collected by your doctor as part of your "normal" care and is added to your medical file (for example, previous conditions, treatments and test results). 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. More information about this data collection and the registry is on our website: [www.eurreb.eu](http://www.eurreb.eu) (section Patients Information).

**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.

Some of these modules also have special patient questionnaires. These questionnaires have been developed in consultation with Dutch and other European patient organizations for these conditions, which are also represented in study groups. In the future, more modules will be developed for other conditions.

**Why am I being approached?**

You have a condition that we collect data on in this registry. Your doctor or patient organization has therefor given you this information leaflet.

**What does participation mean?**

Coded information is taken from your medical record. No additional tests are done. We ask you to help with data collection by answering some patient questionnaires about patient-reported outcomes like quality of life or pain. If you provide medical information, it will be included in the registry.

We use your coded data for research. This means no traceable information, such as your name or address, is shared. Researchers cannot contact you directly, as your address is not stored. General reminders may be sent if questionnaires are still open. The person who uploads your data can also send a reminder through the system. Only the person who uploads your data can link it; no one else has access to do so. Data is entered on a secure website. No one else can identify people in the registry, not even the project management team. If you choose to be in the registry, you can view your own data if you wish. You will need to provide an email address for access. You can change your consent at any time.

Because the registry is designed for long-term results, data will be stored for as long as the registry exists, and for 10 years after it ends. This is because there are few patients with your rare condition. You may always choose to stop data collection.

**What is expected of you?**

Nothing. No extra tests are done. You can choose to fill out patient questionnaires. For this, please leave your email address on the consent form and keep an eye on your spam box. Access codes will be sent to this email, and you must activate your account.

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

We see no disadvantages to participate. Participation is not mandatory.

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

If you do not want to participate, your doctor will assume that you do not want your information stored and shared. Your treatment will not be affected by your decision.

If you do participate, you can change your mind and stop at any time without having to explain why. You need to inform your doctor or do it yourself on the website. Per your request all your data 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**

Your participation in the registry ends if:

* you choose to stop;
* the registry ceases to exist;
* EuRREB, the regulatory authorities or the ethics committee decides to end the registry.

There are annual updates on the outcomes, which are posted on the EuRREB website. You can view these or sign up for newsletters.

**Use and storage of your data**

For this registry, your coded personal data will be collected, used, and stored. This includes health information. Collecting, using, and storing your data is needed to answer questions of studies. The results will be published in scientific journals, on the registry’s website, or shown on social media of the registry or the European Reference Networks. Results can only be shared after approval by a special committee that includes patients. All shared data cannot identify you personally.

The Core Registry collaborates internationally with:

* Other (inter)national registries;
* The Reference Networks for rare conditions (ERNs);
* Researchers from scientific/clinical/patient organizations.

In the independent committee for data sharing, multiple doctors, researchers, and patient representatives decide whether data can be shared. For more information: <https://eurreb.eu/about/data-access-committee/>.

**Confidentiality of your data**

To protect your privacy, your data will be coded. Your name and other identifying information are removed. Data can only be linked to you with the code key, which remains safe at the Leiden University Medical Center (LUMC).

In reports and publications, data cannot be traced back to you. Data is stored centrally in a certified, secure electronic database under European data protection laws. This database is in the Netherlands and managed by LUMC.

**Transfer outside the European Union (EU)**

Your coded data may also be sent to countries outside the EU. In those countries, EU data protection rules do not apply. We will ensure that your privacy is equally protected by signing a data-sharing agreement.

**More information on your rights**

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

**1. Inform**

Your medical file will note your participation. No one else will be informed.

**2. No payment for participation**

You will not receive any payment for participating in this 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 to participate and I know that joining is voluntary. I also understand that I can choose to stop at any time without giving a reason.

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| --- | --- | --- | --- | --- |
| With this consent form, I give permission for: |  |  | | |
|  | **YES** | **NO** | | |
| 1. My data being collected in the Core Registry. My data can be kept for as long as the registry exists, and for 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 personal data being shared in the Core Registry with third parties as described above. The condition is that my privacy is protected with a sufficient level of security or contractual precautions are taken if my data is transferred outside the EU. |  |  | | |
| 1. I give permission to contact me to fill out questionnaires. |  | |  |
| 1. I would like to receive the newsletters from the registry. |  | | ☐ |
| 1. I give permission to record information about any gene mutations related to my condition in the registry. |  | |  |

**Patient's Name / Patient's legal representative name:**

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Signature: Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

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I declare that I have fully informed this patient. If information becomes known during participation that could affect the patient's consent, I will inform him/her in a timely manner.

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

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Signature: Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

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