The Core Registry: A European Registry for rare endocrine, mineral and bone disorders

Dear sir/madam,

We would like to ask you to share your data with The Core Registry. Participation is voluntary. We do, however, need your written consent to participate.

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

Why was this Registry set up?
The European Union has established networks for rare diseases. Two of these networks are the European Reference Network (ERN) on Rare Endocrine Conditions (Endo-ERN) and the European Reference Network on Rare Bone Diseases (ERN BOND), for more information on these networks see http://www.endo-ern.eu/ and http://www.ernbond.eu/. These networks are tasked with improving care for people with a rare disease in Europe. They do this, among other things, by collecting as much information as possible. The Core Registry contributes to this.
The Core Registry is therefore a collaboration of the Registry for rare endocrine conditions (abbreviated in English as **EuRRECa**), and for rare bone and mineral conditions (abbreviated in English as **EuRR-Bone**).

This European Registry was set up to collect data from people with a rare endocrine, bone or mineral disorder. A registry is a database containing a series of coded medical data. It is a collaboration of doctors in different countries within and outside Europe.

What is the goal of a registry?
Registries are very often used by doctors, patients and scientists to gain more knowledge about rare diseases or to monitor the quality of a treatment. Registries can help improve our knowledge on these conditions and the care for people with one of these conditions. Registers can connect care and research.

The Core Registry collects important basic information about your condition(s). This information is also collected by your doctor as part of your “regular” care and is included in your medical record (e.g. previous conditions and treatments and test results). For some diseases, more information is collected in a so-called disease-specific data collection: the condition specific module. As a patient, you get access to the registry to see what is being collected. If you want access, your e-mail address (to be entered on this form) will be shared with the projectteam to create an account. You can find more information about the data collection and the registry at www.eurreb.eu.

Inside The Core Registry there are specific modules for the for the following diseases:

- Pituitary tumors
- Rare phosphate disorders

- Fibrous Dysplasia/McCune Albright syndrome
- Osteogenesis imperfecta
- Parathyroid cancer
- Achondroplasia
- Pseudohypoparathyroidism
- Melorheostosis
- Rare obesity

In the future more modules will be developped for other conditions. If you have one of the above conditions, more information can be entered. Some of these modules also have questionnaires especially for patients. These questionnaires were added in consultation with the European patient associations who are also represented in the various studiegroups.

Why am I approached?
You have a condition about which information is collected in this registry. Your attending physician or patient association has therefore provided you with this information brochure.

What does participation mean?
The coded data is taken from your medical file. So no extra tests are being done.
We will ask you to contribute to the data collection yourself by answering a number of questionnaires for patients. These are about patient-related outcomes, such as quality of life or pain. If you have provided medical information this will be entered in the registry.

We conduct research with your encrypted data. This means that no traceable information, such as your name or address details, is shared. Researchers cannot contact you personally, because your address details are not registered. However, general reminders can be sent if questionnaires remain open. The uploader of your data can also send a reminder via the system.

Only the person uploading your data can link the data nobody else. The data is entered on a secured website. No one else will be able to identify people on the registry, not even the people who created the registry and the projectmanagement team. If you choose to be included in the registry, you can, if you wish, view your own data. To do this, you must provide an e-mail address so that you can access the registry. You can always change your consent.

Since the registry is designed to look at long-term results, the data is kept 30 years (including after death). This was chosen because there are few patients with your rare condition. You can always choose to have your data collection stopped.

What is expected of you?
Nothing. No additional research is done. You can therefore choose to complete the patient questionnaires yourself. Keep an eye on your spam box if you want access. The access codes will be sent to this email address. You must then activate your account yourself.

What are the possible cons and risks of The Registry?
We don't see any downsides to participating. Participation is not obligatory.

If you do not want to participate or want to stop the study?
If you indicate on the enclosed sheet that you do not wish to participate, your treating physician will assume that you do not wish your information to be stored and shared. Your treatment will not be affected by your decision.

If you do participate, you can always change your mind and still quit. You don't have to say why you're quitting. However, you must report this to your doctor and you can also indicate this yourself on the website. The data collected up to that point will be used for the research.

End of research
Your participation in the study ends if:

- you choose to stop;
- the end of the registry has been reached;
- EuRRECa, EuRR-Bone, the government or the reviewing medical ethics committee decides to stop the study.

There are annual updates on the results. These are placed on the EuRRECa/EuRR-Bone website, so you can always view the results. You can also register for the newsletters.

Usage and storage of your data

Your coded personal data is collected, used and stored for this research. It concerns data about your health. The collection, use and retention of your information is necessary to answer the questions asked in this survey. The results will be published in scientific journals, the registry's website or displayed on the social media of the registry or the rare disease network. Results can only be shared if these have been approved by a special committee. Patients are also members of this committee. In addition, it is good to know that only anonymous data is passed on when results are shared. The registry cooperates internationally with others:

- Other (inter)national Registries;
- The reference networks for rare diseases (ERNs);
- Researchers from scientific/clinical/patients organizations.

The independent committee set up to review data sharing includes multiple physicians, researchers, and patient representatives. Data will therefore only be shared if permission has been given by this committee. For more information see: https://eurreb.eu/about/data-access-committee/.

Confidentiality of your data
To protect your privacy, your data is assigned a code. Your name and other data that can directly identify you are omitted. Data can only be traced back to you with the key of the code. The key to the code remains safely stored in the center that is uploading your data.

The data in reports and publications about the research cannot be traced back to you either. The data is centrally stored in an electronic, certified, secure database. It falls under European data protection regulations. This database is currently located in the Netherlands and is maintained by the LUMC.

Transfer to countries outside the European Union (EU)
In this study, your encrypted data may also be forwarded to countries outside the EU. In those countries, the rules of the EU for the protection of your personal data do not apply. However, your privacy will be protected on an equivalent level.

Learn more about your rights when processing data
For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority.

1. To inform
A note will be made that you are participating, this can be stored in your medical file. Furthermore, no others will be informed about this.

2. No compensation for participation
You will not be paid for participating in this study.

3. Do you have questions?
If you have any questions or complaints about the study, please contact: registries@lumc.nl. If you prefer other way, you can contact the LUMC complaints officer via the Complaints Team at the Patient Service Bureau, Location H2-11,
PO Box 9600, 2300 RC Leiden. For more information about the processing of personal data, or if you want to exercise one of your rights, please contact the LUMC data protection team via privacy@lumc.nl.

4. Signing consent form
Once you have had sufficient time to think about it, you will be asked to decide whether to participate in this study. If you give permission, we will ask you to sign the corresponding permission statement. Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention and cooperation, also on behalf of all other LUMC doctors who contribute to the registry.

Dr. Natasha Appelman-Dijkstra, Endocrinology department and coordinator EuRR-Bone
Prof. Dr. Nienke Biermasz, Endocrinology department
Prof. Olaf Dekkers, Endocrinology department and chair of Data Access Committee Dr. Carmen Vleggeert, Neurosurgery department
Dr. Abbey Schepers, Surgery department
Dr. Peter de Witte, Orthopedics department
Dr. Demien Broekhuis, Orthopedics department

Informed 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 adequately answered. I had enough time to decide whether to participate and I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I don't have to give a reason for that.

With this consent form I give permission for:

	Yes	No
1. Collection of my data in the Core Registry and that my data is kept indefinitely.	☐	☐
2. I also want access to this information myself. For this, the access codes will be sent to the following email address: Click or tap here to enter text	☐	☐
3. I agree that my personal data in the Core Registry are shared with third parties as described above. The condition is that a sufficient level of protection for my privacy is guaranteed or sufficiently contractual precautions are taken when these data become sent outside the EU.	☐	☐
4. I give permission to contact me for filling in questionnaires	☐	☐
5. I would like to receive the register's newsletters	☐	☐
6. I give permission to record information about any gene mutations of my condition in the Registry	☐	☐

Name of the subject

_____

Signature : Date :

_____

I declare that I have fully informed this subject about the mentioned research. If information that could influence the subject's consent becomes known during the research, I will inform him/her in time.

Name of the researcher (or their representative): _____

Signature: Date :

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