European Reference Network | eUROGEN Urogenital Diseases

PATIENT INFORMED CONSENT FORM

Dear Patient or parent/legal representative,

We invite you or your child/the patient[1] to take part in a patient registry for rare urogenital diseases. Participation is voluntary and requires your written consent as a legal basis to use your data. Please read this information carefully and ask your medical doctor or the medical doctor of your child/the patient for explanation if you have any question.

EUROPEAN REFERENCE NETWORK REGISTRIES

- Rare and complex urogenital conditions may require surgical correction or other therapy, often during the neonatal period or in childhood. Individuals affected require life-long care provided by multidisciplinary teams of experts who plan and perform surgery and provide post-operative long term multidisciplinary care.
- European Reference Networks (ERNs) are networks of healthcare professionals for rare diseases across Europe working together to support patients with rare and complex diseases.
- ERN eUROGEN is the ERN for rare urogenital diseases and complex conditions (https://eurogen-ern.eu/for-patients/).
- To understand the course of a disease and investigate new diagnostic procedures and treatments in order to improve patient care, ERNs need databases (also known as “registries”) for research and knowledge development.
- To build such registries, data from many patients must be combined. We ask for your consent to include your data or the data of your child/the patient in the ERN eUROGEN registry to perform research, as described below, in accordance with national and European data protection laws and ethics guidelines[2].
- 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 and their long-term outcomes.
- Data privacy will be secured as described below in this form. Only the doctor and the persons who will register the data will be able to link the data to the patients. Therefore, the risk of re-identification by unauthorized persons is minimal.
- In the English-language video, which you can watch via the QR code below, an explanation of what participation entails is provided. You can turn on Dutch subtitles by using the gear icon.

[1] Adult for whom you are legal guardian

[2] including the European General Data Protection Regulation (GDPR), Reg. (EU) 2016/679; the Declaration of Helsinki 2013; the International Ethical Guidelines for Biomedical Research Involving Human Subjects CIOMS-WHO (2016); the Oviedo Convention and its Additional Protocol on human rights and biomedicine, concerning biomedical research (2005); the “standard contractual clauses for the transfer of personal data to third countries” (EU) 2021/914 and **…. <please include any other applicable law>**

VALUE & BENEFITS

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 urogenital diseases and complex conditions.

Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered.

Only users authorised by a special committee (consisting of the Project Steering Committee and Advisory Board) can use the data. This committee is composed of qualified health professionals, patients' representatives as well as members with legal and ethical expertise. It ensures that the request for data use aligns with the purposes of the registry and its policy.

The committee may provide data access to **clinical researchers from within or outside ERN eUROGEN, patient organisations, and the pharmaceutical industry** in order to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases**.** Also, registry data may be shared with **health authorities, policy makers and regulators** to inform their decisions on rare disease health policy and approval of medicines.

Data use for commercial purposes

Companies might request access to data stored in the registry to perform research aimed to develop new therapies for the condition. For example, the registry can inform companies how many patients live with a certain disease and help find patients in clinical trials of new therapies.

Typically, the results of this research will become property of the company that may also use them for further **commercial purposes** and to patent. You or your child/the patient will not acquire any rights over these results, own them in any way, or be entitled to share any future financial benefit derived from this research.

You may choose if you want to allow the use of the data for commercial research.

Data transfers outside the EU

Data without any personally identifiable information may also be forwarded 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. Data will only be transferred if the project adheres to the goals of the registry and was approved by the special committee. You may choose if you want to allow the transfer of the data to non-EU countries.

Future changes in data collection

To gain more insight on your condition or the condition of your child/the patient we may need additional data in the future. Which information we collect will be published on the registry website https://eurogen-ern.eu/what-we-do/the-eurogen-registry/.

In the event a disease-specific subregistry exists for the rare urogenital disease or complex condition you or your child/the patient suffers from, more detailed clinical data will be collected. Such subregistries are of great importance to better understand the precise nature of rare diseases. More information on the available subregistries can be found on the registry website.

Furthermore, we may request additional data from existing databases/registries, such as ARM-Net or registries from other ERNs. You may choose if you want to allow the linking of the data with additional data as described above.

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 your medical doctor or 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. Your current care or the 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 you or 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 information about projects given access to registry data is publicly available on the registry website. The results of the research will be shared with the scientific community by publications in scientific journals where personal data are not provided. In addition, results will be communicated through the ERN eUROGEN website. The privacy of your data will always be protected as described below.

PROTECTION

WHAT ARE THE RIGHTS OF THE REGISTRY PARTICIPANT?

- You decide whether you or your child/the patient participates in the registry. Please take as much time as you need to make this decision. Participation is voluntary. You can decline participation without giving any reasons. You or 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. Your doctor 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 will be processed and who will have access to it. You can also request to access your data or the data of your child/the patient at any time.
- The hospital where you or 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 is processed, you would like more information or to exercise your rights, you may contact the Data Protection Officer (<please replace with contact details (postal address and email address) of your local Privacy Officer>), or you may raise a complaint to the <please replace with the name of your national privacy authority>.They have the duty to ensure the data is processed safely and to notify you if a breach of data security occurs. Any inquiries should be addressed by the Data Protection Officer within 30 days.
- For all data submitted to the **central registry database**, the Radboud university medical centre, Nijmegen, The Netherlands and its principal investigator Wout Feitz is responsible for the protection of the data, its storage, use and access: Wout Feitz, Radboudumc, internal postal number 610, postbus 9101, 6500 HB Nijmegen, The Netherlands, secretariaat.uro@radboudumc.nl.
- When your child will reach 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 very secure electronic systems. As the registry involves collecting information from many centres, the system will be 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 your or your child's/the patient's name, address and hospital number will not be recorded. All patient data will be pseudonymised before being stored in the registry. This means that all identifiers that relate to you or your child/the patient will be removed and replaced by a pseudonym[3]. Only the medical doctor and the persons who will register your data can link the pseudonym to the patient. Therefore, the risk of re-identification by unauthorized persons is minimal.
- 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.
- 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.
- The registry data will be stored on a secure server in The Netherlands. As the registry is designed to look at long term outcomes, the data will be stored for at least 25 years. After this period, the need for keeping the stored data in the registry will be reviewed every 10 years by the ethical committee of the Radboudumc.

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 the 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

Costs

Participation in this registry will not entail any costs for you.

Insurance

<please include information about insurance taken for the registry activities if applicable, as requested by some Ethics Committees – otherwise, please delete this paragraph>

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

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More information is available on the website https://eurogen-ern.eu/what-we-do/the-eurogen-registry/. If you have any other question about the registry, please contact: <please fill out the name and e-mail address of the local Principal Investigator>

[3] 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.

INFORMED CONSENT

Patient First and Last Name:……..……..……

Date of Birth (dd/mm/yyyy):: .. .. / .. .. / .. .. Email address:……

I am the: ☐ patient ☐ parent ☐ legal representative[4]

First name and last name of the parent / legal representative:……..……..

I have read the information sheet about the ERN eUROGEN registry.
I have been given the time and opportunity to ask questions about the objectives of the registry and the use of the data and that I have solved all my doubts with the medical doctor.
I understand that participation is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting future medical care for me or my child/the patient.
I approve that my data or the data of my child/the patient will be stored in the ERN eUROGEN 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 the 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 pseudonymized data of me or my child/the patient may also be **used to support commercial projects** aimed to improve healthcare.
		I CONSENT that thepseudonymized data **may be transferred to non-EU countries, in compliance with GDPR,** to support projects aimed to improve healthcare.
		I CONSENT thatthe pseudonymized data may be **linked to existing databases/registries** to improve healthcare.
		I WOULD LIKE TO BE CONTACTED bythe medical doctor about any **research project and/or clinical study related to my condition or that of my child/the patient.**
		I CONSENT to receive in the future, if applicable, a **link to an online questionnaire** on the email address above.

PATIENT OR PARENT/LEGAL REPRESENTATIVE	MEDICAL DOCTOR / AUTHORISED WITNESS
Date and Signature:	Full name: Position: 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.

[4] *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.*