Department letterhead or stamp

Patient informed consent for storage and use of patient data within the international research project ”ESID Registry”

Information for Patients

Dear patient, dear parents,

We would like to ask for your consent to participate in a research project. This document provides a summary of this project. Please read it carefully and ask your attending doctor if anything is unclear to you.

Your clinic indicated above participates in the research project “ESID (European Society for Immunodeficiencies) online Patient and Research Registry” (**ESID Registry**). This is a **European internet database** with **password-protected access**. The ESID Registry is coordinated and maintained at secure servers at the Medical Center – University of Freiburg, Germany. The contact details of the coordinator are provided below.

Aim of the project

The aim of this project is to collect data on patients with primary (inborn) immunodeficiency diseases (PID) to build up a knowledge base for these rare diseases that supports physicians to improve diagnosis, classification, prognosis and therapy for their PID patients. For this, data on clinical symptoms, laboratory values, treatment and the clinical course of the disease are collected in a standardised form from centres treating PID patients all over Europe.

At initial registration, data on your/your child’s previous medical history will be recorded. To learn about the long-term prognosis, the data base allows ongoing documentation (at least once per year) of each new medical data. All patient data is stored long-term for an indefinite period of time in the ESID Registry.

Depending on the extent of your consent, your data/your child’s data can be made available to cooperating **research institutes**, such as medical centers specialized in treating PID, research laboratories that investigate the causes of PID, or epidemiologists who study the patterns, causes, and effects of health and disease conditions in defined populations. For this purpose, a formal application of the researcher to ESID is necessary. Data which is made available to such third parties shall only be used for the defined research purpose and must not be passed on to other parties. The respective project must be approved by an independent Ethics Committee.

Depending on the extent of your consent, a subset of your data/your child’s data can also be made available to **pharmaceutical companies** who financially support the project. These companies use the data to identify the needs for drug development, to estimate the demand for certain products (e.g. immunoglobulins), to learn about side effects and to improve existing medication or develop new medication. The pharmaceutical companies who may receive your encrypted data (see below) may be located in a different country with lower levels of data protection compared to the country in which you receive your medical care.

Please contact the project coordinator (contact details given below) to receive a list of the companies that currently fund the project and are therefore eligible to receive registry data.

No one else except these institutions will be granted access to your data. Under no circumstances your data will be made available to unauthorized third parties e.g. insurance companies. Publications basing on patient data will always be performed using anonymized data.

Data Storage Security

Only patient data relevant to your medical condition (including **year** and month of birth, clinical symptoms, laboratory and examination results) are stored and processed automatically **without** your personal data (name, place of residence) on a server at the Medical Center – University of Freiburg. Your attending doctors (or documenting assistants) can store your personal data on a separate server. This data is never made available to third parties.

Any data that is made available to third parties is **coded** double. Coding means that the data is labelled with a numerical code. In this way, it is possible for researchers to make long-term observations and learn about the course of the disease, without identifying individual patients. Only your attending doctors (or documenting assistants) have access to the coding list, that connects your personal data with the numerical code, and thus are able to combine clinical with personal data. They are responsible for securely storing your identifying data and the coding list.

The technical measures described above guarantee the highest possible level of data protection. The system complies with data protection laws and has been approved by the responsible Ethics Committee.

Voluntary participation

Participation in this research project is voluntary and can be withdrawn at any time. Please inform the attending doctor at your centre if you wish to change your mind. There are no drawbacks resulting to you/your child from the refusal to participation.

If you withdraw from the project, you can decide whether your data/your child's data shall be deleted or whether it can be further used after complete anonymisation (i.e. stripping the data off all identifying information, including the code, which makes it impossible to re-identify your data). Please note that data that has already been issued to third parties, such as researchers and pharmaceutical companies, cannot be deleted. No further data on you/your child will be entered in the system after you have withdrawn your consent.

You can ask your doctors at any time to provide you with the data that is stored in the registry and ask them to correct any data errors.

Contact information

If you have further questions on this research project, please ask your doctor or directly contact the ESID Registry coordinating team in Freiburg:

ESID Registry, c/o Dr. Kindle, Universitätsklinikum Freiburg, CCI, Engesserstr. 4, D-79108 Freiburg.
E-Mail: esid.registry@kenes.com, Tel.: +49-761/270-34450, Fax: +49-761/270-36960, Web: http://esid.org.

If you decide to participate in this project, we kindly ask you to fill in and sign the consent form below.

Consent form

International research project "ESID Registry"

I hereby give my consent to participate in the aforementioned research project.

- I have been clearly and fully informed by _____ about the nature, scope and aims of the research project. I have carefully read and understood the patient informed consent. My attending doctor has answered any questions that I had concerning the registry.
- I have had sufficient time to ask questions and make my decision.

I have been informed that I can withdraw my consent at any time and my data/my child's data will be deleted or completely anonymised on my request. I am aware that data that has already been issued to third parties such as researchers and pharmaceutical companies cannot be deleted.

I have received a copy of the patient informed consent form. The original copies remain with my attending doctor.

Data protection

I give my consent that my medical data/my child's medical data is recorded as part of the research project and can be used anonymously e.g. for publications.

Please tick the appropriate options:

☐ Yes ☐ No I give my consent that my medical data/my child's medical data that is recorded as part of the research project "ESID Registry" is made available to **cooperating research institutes** as described in the patient information. I am aware that these institutes may be located in other countries with lower levels of data protection.

☐ Yes ☐ No I give my consent that my medical data/my child's medical data that is recorded as part of the research project "ESID Registry" is made available to **pharmaceutical companies** as described in the patient information. I am aware that these companies may be located in other countries with lower levels of data protection.

A: Adults

Date		Patient's signature	
		Name of doctor	
Date		Doctor's signature	

B: Minors or legally incompetent persons

Date		Parent's or legal representative's signature	
Date		Second parent's signature (optional)	
Date		Child's/patients signature (optional)	
		Name of doctor	
Date		Doctor's signature	