



Stamp or letterhead of the department

## Patient information and declaration of consent for the storage and use of patient data within the framework of the research project "ESID-Registry"

### Patient information

Dear patient or parent,

We would like to offer you the opportunity to participate in a research project. Outlined below you will find detailed information on this research project.

Please read this patient information carefully. Your attending physician will also talk you through this information. Please ask your doctor if you do not understand something or if you would like to know more.

In cooperation with ESID (the European Society for Immunodeficiencies), the above mentioned department conducts the study project "International Register of Clinical and Laboratory Chemical Parameters for Primary Immunodeficiencies" (short: "**ESID Registry**"). This is an **international, access-protected internet database**.

This database is stored, operated, and maintained on secure servers at a certified European clinical trial and registry provider. The contact details can be found at the end of the information leaflet.

### Aim of the research project

The aim of the project is to combine clinical and laboratory data of patients with primary, i.e. congenital immunodeficiencies (PID) in order to improve diagnosis, classification, prognosis, assessment and ultimately therapy. When you first register, data on you or your child's medical history will be collected. The database also enables continuous long-term documentation. This allows new insights into all patients with the same rare diagnosis to be gained and incorporated into treatment.

The data stored within the scope of the study project are not routinely deleted, but stored indefinitely in the database to facilitate a long term assessment of outcomes.

### Secure storage of your data

The collected case-related data e.g. **year** of birth (and up to 12 years of age also the **month** of birth, but not birthday), laboratory values and test results as well as the type of genetic mutation causing the disease (if available) are entered into the Internet database by the attending physician or a documentation specialist and stored using a pseudonym. By using this pseudonym, a researcher can observe the study data over many years in order to learn from the course of the disease. The data will not be traced back to your person/child. Your identifying data (e.g. name, place of residence) can be stored by your attending physician or a documentation specialist on a separate server to which third parties have no access. Only the attending physician or documentation specialist can trace the data back to you/your child. In order to guarantee IT security and IT operation, your data can - if necessary - also be processed by administrators of the technical operator who are commissioned by ESID with the operation of the system and are bound by appropriate data protection regulations. The EU wide legal provisions on data protection are met. The study project has been reviewed and approved by the responsible ethics committee.

### Secure transfer of your data

Patient information and declaration of consent „ESID-Registry“

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If you are in principle willing to provide your data/your child's data to the ESID Registry, you have the following options:

You may choose to make your data available only to ESID for research purposes (by signing the last page without selecting any of the options shown in the "Use of data" box).

**Option 1:** You may also choose whether your data/your child's data may be made available to **cooperating research institutions**. These may be medical centres focusing on rare immunological diseases, research laboratories studying the causes of congenital immunodeficiencies or European networks of researchers and physicians and epidemiologists (researchers working on the distribution and causes of diseases and health conditions). Data passed on to third parties may only be used for the research project applied for at ESID and may not be used or passed on by the recipient for other purposes. The project must have been ethically and legally reviewed and evaluated by an independent ethics committee.

**Option 2:** Furthermore, you may choose whether your data/your child's data may be passed on to **industrial partners**, e.g. pharmaceutical companies that support the project financially. They use the data, for example, to develop new drugs or to improve existing therapeutic options.

In both cases, your data/your child's data may also be passed on to recipients in countries outside the EU, if the European Commission has recognized that the respective country has adequate legal data protection in place.

**Option 3:** In addition, you may also specify that data may be transferred to research partners in **third countries** for which this requirement is not met. These countries may have a lower level of data protection than the EU. There is therefore a risk that public or private bodies may access your data, although this would not be permitted under European data protection law. In addition, you may have fewer or less enforceable data subjects' rights and there may be no independent supervisory authority to assist you in enforcing your rights. In this case, your data can only be passed on if you have expressly consented to this. You may also (additionally) tick the corresponding box in the declaration of consent.

Before your data is passed on, it will be pseudonymised individually for each recipient in an additional step ("double pseudonymisation").

**Apart from the aforementioned institutions**, no one has access to your data. Under no circumstances will the data be made available to any unauthorised third parties such as insurance companies. Any scientific or technical publications based on the data will preserve the anonymity of you or your child.

### **Voluntary participation and rights**

Participation in this study project is voluntary and you have the right to withdraw your participation at any time without giving any reason. Please contact your attending physician or the department of your treatment centre mentioned above. If you do not participate in this study project, you/your child will not experience any disadvantage.

In the event of revocation, you can decide whether your data/your child's data should be deleted under your right to be forgotten in European legislation (GDPR) or whether it may be retained and used anonymously (i.e. the pseudonym is deleted, the data can no longer be traced back to you/your child) for further research projects. Data analysis that precedes study withdrawal cannot be undone. From the time of your revocation, no new data will be entered into the database on you or your child.

You have the right to request information about the data stored (**right of access**) from the attending physician at any time and to receive a free copy of this data. You have the right to have erroneous data corrected (**right to rectification of data**) and the right to block your data under certain conditions (**right to restriction of data processing**).

## Questions regarding the study or data protection

Should you have any further questions regarding the study project, data protection or any of your rights, please contact the physician providing the information, your treatment centre, the study leader or the central contact point.

You can also contact the supervisory authorities responsible for you or your centre. You can obtain the relevant contact information for example via the website of the Information Commissioner's Office (ICO) for Data Protection in the UK, the Federal Commissioner for Data Protection in Germany or at any time via the central contact point, your attending physician or your treatment centre:  
<https://ico.org.uk> or [https://www.bfdi.bund.de/DE/Infothek/Anschriften\\_Links/anschriften\\_links-node.html](https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html)

### Central contact point

ESID-Registry  
European Society for Immunodeficiencies (ESID)  
Mijnbouwstraat 23 Delft  
Niederlande  
Chairperson of the registry working party  
Email: [registry@esid.org](mailto:registry@esid.org)  
Homepage: <https://esid.org/Working-Parties/Registry-Working-Party/ESID-Registry>

#### Local registry coordination

Name:

Department:

Contact:

Local contact person's name:.....  
Email .....Tel. ....Fax. ....

### Responsible body for data processing

The responsible body for the data processing in this study is ESID, represented by the ESID Executive Board, which is represented by the Chairperson of the ESID Registry Working Party (also a member of the Executive Board). The ESID Executive Board is determined by election within the ESID members.

Information on ESID, the ESID Registry, the Chairman of the Registry Working Group and contact details are regularly made publicly available on the ESID website (<https://www.esid.org>) and can also be obtained at any time from your attending physician, your treatment centre or via the central contact point.

### Right of appeal

You have a right to complain if you believe that the processing of your personal data violates your privacy rights (**right to lodge a complaint**).

You can obtain the contact information of the supervisory authority responsible for you or your centre for example via the website of the Information Commissioner's Office (ICO) for Data Protection in the UK or at any time via the central contact point, your physician or your treatment centre:  
<https://ico.org.uk>

### Participation in the study

If you decide to participate, we ask you to complete and sign the declaration of consent form.



(Patient Label)

## Declaration of consent

### **International registry with clinical and laboratory parameters for primary immunodeficiencies ("ESID Registry")**

I give my consent to participate in the aforementioned study.

- Mr. / Mrs. / Dr. / Prof. \_\_\_\_\_ informed me in detail about the nature, meaning and scope of the study project and I have understood the information given. I have also read and understood the text of the patient information and this declaration of consent. Questions arising have been answered to my satisfaction.
- I have had sufficient time to ask questions and to make an informed decision.

#### **Data usage**

I agree to the pseudonymised recording, storage and use of the disease related data collected about me/my child within the scope of the study project for ESID research purposes, including their anonymised use for the presentation of research results in word and illustration.

Please tick the appropriate box:

Yes  No

I agree that within the scope of the study project "ESID-Registry" my case-related data/the case-related data of my child will be stored, processed and forwarded in the way described above to **cooperating research institutions** in a double pseudonymised form. My data may also be passed on to recipients in countries outside the EU if the European Commission has determined that the country has an adequate legal level of data protection. I have the right to request information about my/my child's case-related data and personal data processed in this study and to receive a free copy of this data. I have the right to request the rectification, restriction of processing or completion of my /my child's case-related data (option 1).

Yes  No

I agree that within the scope of the study project "ESID-Registry" my case-related data/the case-related data of my child will be stored, processed and forwarded in the way described above to **industrial partners** in a double pseudonymised form. My data may also be passed on to recipients in countries outside the EU if the European Commission has determined that the country has an adequate legal level of data protection. I have the right to request information about my/my child's case-related data and personal data processed in this study and to receive a free copy of this data. I have the right to request the rectification, restriction of processing or completion of my /my child's case-related data (option 2).

Yes  No

**In addition, I consent to the transfer of my data to countries outside the EU, even in cases where the European Commission has not taken an adequacy decision. I have been informed about the possible risks of such a transfer (option 3).**

I have been informed that I can withdraw my consent at any time (**data protection right of revocation**) and that existing data will be deleted or made completely anonymous at my request (**right to erasure**). I am aware that it is not possible to delete data that has already been extracted from the registry for analysis and publication and passed on to third parties.

I have received a copy of the patient information and the declaration of consent. The original remains with the Study Centre.

**A: Consent adults**

Date	<input type="text"/>	Patient's signature	
	Name of the person obtaining consent		
Date	<input type="text"/>	Signature of the person obtaining consent	

**B: Consent of minors or persons incapable of legal activity**

Date	<input type="text"/>	Signature of the individual with legal parental rights for the patient	
Date	<input type="text"/>	Signature of the second person having the custody rights* If applicable	
Date	<input type="text"/>	Signature child/patient** if applicable	
	Name of the individual obtaining consent		
Date	<input type="text"/>	Signature of the person obtaining consent	

\* In principle, both parents are required to sign. If only one parent has signed, the person signing also affirms that he or she is acting in agreement with the other parent or that he or she has sole custody of the child.

\*\* In the case of minors, the consent of the patient and the custodian is generally required up to the age of 14. When the patient reaches the age of majority, a new declaration of consent is required from the patient under point A (consent of adults).