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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, Dear parents,

We would like to invite you to participate in a research project. Below you will find information about this research project.

Please read this patient information carefully. Your doctor/nurse will also talk to you directly about the project. Please ask your doctor/nurse if you have any questions or doubts or if you would like to learn more about this study.

In cooperation with the ESID (European Society for Immunodeficiencies), we in St James's Immunology department are participating in "International Register of Clinical and Laboratory Parameters for Primary Immunodeficiencies" (short: "**ESID Registry**"). This is an **international, access-protected internet database**.
This database is stored and maintained on secure servers at the University Hospital Freiburg, Germany, EU.

Aim of the study project

The aim of the study project is to combine clinical and laboratory data of patients with primary, i.e. congenital immunodeficiency (PID) in order to improve diagnosis, classification, prognosis assessment and ultimately therapy. When you first register, data on your/your child's medical history will be collected. The database furthermore enables continuous long-term documentation. This will help us understand these rare conditions and may benefit other patients with similar conditions. .
For that reason it is intended that the data stored entered on the registry will be stored indefinitely in the database.

Secure storage of your data

The collected data (e.g. **year** of birth and for children up to 12 years of age also the **month** of birth (not birthday), laboratory values and test results as well as the type of mutation causing the disease) are entered into the Internet database by your doctor/nurse or or a documentation specialist and stored on a server at the University Hospital Freiburg, Germany, EU using a pseudonym (not your real name). By using this pseudonym, a researcher can follow the study data over many years in order to observe and learn from the course of the respective disease. The data will not be traced back to your person/child. Your identifying data (e.g. name, place of residence) will be stored in a secure, password protected computer in St James's hospital to which third parties have no access. Only your doctor /nurse 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 University Hospital Freiburg, Germany, EU, who are commissioned with the operation of the system and are bound to secrecy. The legal provisions on data protection are met. The study project was reviewed and approved by the responsible ethics committee in Germany and also in Ireland (Research ethics , Tallaght University Hospital: REC reference: 2019-09 List 33(8).

Secure transfer of your data

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).

Other options:

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 congenital immunodeficiencies, research laboratories studying the causes of congenital immunodeficiencies 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. Scientific publications based on the data will alsopreserve the anonymity of your person/child.

Voluntary participation and rights

Participation in this study project is voluntary and you have the right to withdraw your participation (revocation) at any time without giving any reason, simply by contacting your doctor/nurse or the Immunology department. If you choose not to participate in this study project, you/your child’s treatment will not in any way be disadvantaged.
In the event of revocation, you can decide whether your data/your child's data should be deleted or whether it may be used anonymously (i.e. the pseudonym is deleted, the data can no longer be traced back to you/your child) for further research projects. However, completed processing or releases

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 your doctor/nurse 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 your doctor/nurse, or the immunology department. .

You can also contact the relevant regulatory authority:

Data Protection Commission
21 Fitzwilliam Square South
Dublin 2
D02 RD28
Ireland
www.dataprotection.ie

Central contact point

Database of patients with Immnodeficiency in Ireland: in conjunction with ESID
Immunology Department, St James's Hospital, Dublin

Tel.: +353 1 4162928,

E-Mail: immunologymail@stjames.ie

Responsible for data processing

Dr David Edgar, Consultant Immunologist , St James's Hospital is responsible for the data management locally whilst the overall ESID registry is managed by the ESID Registry Working Party , who are in turn accountable to the ESID Executive Board. The board is elected by 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 doctor/nurse or treatment centre.

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)**. If your complaint cannot be resolved through discussion with your doctor/nurse, you may contact the patient experience office at St James's hospital

Patient Experience Office, CEO Building, St. James's Hospital, James's Street, Dublin 8,
Email: patientfeedback@stjames.ie

or by appointment by calling the Patient Experience Office on 01 4284248 or 4103361.

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. _____ informed me in detail and comprehensibly about the nature, meaning and scope of the study project. I have also read and understood the text of the patient information and this declaration of consent. Questions that arose were answered comprehensibly and sufficiently.
- I had enough time to ask questions and to decide.

Data usage

I agree to the pseudonymised recording, storage and use of the disease 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 may 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		Patient's signature	
	Name of the physician obtaining informed consent		
Date		Signature of the physician obtaining informed consent	

B: Consent of minors or persons incapable of legal activity

Date		Signature of the custodian / legal representative of the patient	
Date		Signature of the second person having the custody rights*	
Date		Signature child/patient** if applicable	
	Name of the physician obtaining informed consent		
Date		Signature of the physician obtaining informed consent	

* Generally, 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 case of minors, the consent of the patient and the custodian is generally required as of 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).