ECFS Patient Registry (ECFSPR)

Informed Consent - Information sheet

Registries for:
- Cystic Fibrosis (CF),
- Cystic Fibrosis Screening Positive - Inconclusive Diagnosis (CFSPID) and
- Cystic Fibrosis Transmembrane Regulator- Related Disorder (CFTR-RD)

collect diagnosis and clinical information about people with CF or a CFTR-RD or who are CFSPID.

Registries for these and other medical conditions and illnesses are used in many countries throughout the world to support medical research and to improve care and treatment.

In our centre (*centre name)* in (*city, country*) we are in the process of establishing / have established (include what is applicable*)* a CF / CFSPID / CFTR-RD registry and we ask your consent to include your data.

The data collected in our centre will be sent, *pseudonymised*, once a year, to the *European Cystic Fibrosis Society (ECFS) Patient Registry ("*European Registry"*).*

1. Why is the collection of data important?

CF and CFTR-RD are rare conditions and collecting data about them from as many people with CF/CFTR-RD as possible will allow the European Registry to measure, survey and compare aspects of CF/CFTR-RD and their treatment in a large number of people. The results will reflect the situation of CF/CFTR-RD across Europe, give us better insight into the disease(s) and aid medical staff and health policy makers to plan and support care. For people who have screened positive for CF but do not have a confirmed CF diagnosis (CFSPID), collecting data will allow clinicians and the European Registry to monitor long-term health outcomes and identify factors that can lead to a person developing CF or a CFTR-RD.

Your participation in the CF/CFTR-RD/CFSPID Registry of (***centre name, city***) and the European Registry will be of great value.

2. What is the ECFS Patient Registry?

The European Cystic Fibrosis Society (ECFS) is an international community of scientific and clinical professionals committed to improving survival and quality of life for people with CF through the promotion of high-quality research, education and care. As part of the ECFS, the European Registry collects data from people with CF, CFTR-RD or who were designated CFSPID at birth, in Europe and partnership countries, in order to have a deeper understanding of the disease(s), to facilitate the introduction of new standards of care, to provide data for epidemiological research and to support public health-planning.

3. What data do we collect?

Personal data e.g. year and month of birth, sex, information relating to diagnosis (newborn screening result, genotype, sweat test and other relevant diagnostic information) are collected when a person is first enrolled in the European Registry;

Clinical data (treatment, lung function, height and weight, infections, complications and transplants) are collected for every calendar year.

The same definitions and ways to represent the collected data elements (variables) are used by all the centres and national registries participating in the European Registry. This means that information can be compared from country to country. You can see more about what data are collected here.

For specific research projects additional clinical data may be collected and processed; this happens when the research purpose is about improving knowledge of CF/CFTR-RD/CFSPID.

4. How do we collect the data?

Some people from the centre are authorised to input data to a secure, online data collection software. This system was developed specifically to collect data from people with CF/CFTR-RD or who were CFSPID. It is made available by the European Registry to authorised centres. Once a year our centre sends the collected and pseudonymised data to the European Registry through this secure software.

5. Who can identify me?

The European Registry is not able to identify you; only your clinician or other authorised medical staff in your centre can do this. A unique patient identifier (ID), which is a random numeric code, is generated by the software when a patient is included in the system. Data sent through the software to the European Registry are linked only to the patient and centre IDs. Using a unique identifier that replaces information that can identify a person is called “pseudonymisation”. Another random numeric code is generated by the software for your centre. Data sent through the software to the European Registry from your centre is linked to the centre code and not the centre name.

6. What are my rights and how do I exercise these rights?

- Participation in our centre (*name, city*) Registry and the European Registry is voluntary. The decision to participate or not does not have any influence on the medical care that you receive.
- You have the right to withdraw your consent at any time without stating a reason.
- You have the right to access your personal data, in accordance with the European General Data Protection Regulation (GDPR) and national legislation on data protection & information security. Please consult your clinician if you would like to withdraw your consent or exercise your rights. Your clinician must contact the European Registry to inform them about your decision (as explained above, the European Registry cannot identify individual patients in the database). The European Registry will then take the necessary action.

- If you withdraw consent for your data to be collected and used as described in this document your data will be deleted from the data collection software and from the most recent, unpublished version of the database. No data for you will be collected in the future but previously published data will not be deleted. This is to ensure the continuity and preservation of the data in the European Registry which is essential to support medical research. It is not possible to exercise your right to change, delete, restrict the processing of data or the right to data portability (i.e. use your data across different services) if the data have been published.

If you believe that your rights have been infringed, you have the right to lodge a complaint with the supervisory authority. For the European Registry we advise you to first contact the Operations Manager (operationsmanager@ecfregistry.eu).

7. How will the data be used?

The data will be used to:

- Contribute to the results of analyses and comparisons of demographic and clinical outcomes of CF/CFTR-RD/CFSPID in (*country name*) and across Europe in the European Registry's Annual Data Reports and Highlights Reports;
- Contribute to scientific research. Researchers, patient organisations and commercial companies can apply for data to use in specific projects. A formal application needs to be submitted. All applications are considered by the European Registry's Scientific Committee in accordance with a strict procedure. You can find out more about this procedure here;
  Data will only be released for research or commercial purposes if there are direct benefits for the people with CF/CFTR-RD or who were CFSPID at birth, and if all ethical requirements have been met;
- Monitor and evaluate if and how care is improving;
- Identify new trends, i.e. an increase in a new infection or complication;
- Help plan current and future services for people with CF/CFTR-RD or who were CFSPID at birth;
- Prepare the landscape for clinical trials on new therapies;
- Monitor the effects of new licensed therapies when these become available;
- Contribute, *anonymously (*the data cannot be linked to an individual) to a future global CF/CFTR-RD/CFSPID registry.

The use of any data from the European Registry requires the final approval of the European Registry Steering Committee. This consists of elected medical specialists who represent the countries participating in the European Registry, a patient representative and a data-controller (the person who is appointed by the ECFS to ensure the data are handled in adherence to the European GDPR). More information about the approval process can be found here.

8. Who can access the data?

Data access is restricted to authorised users only. If authorised, your doctor or other medical staff can access the data-collection system to enter and modify data. In order to fulfil the purposes of the European Registry the following people will also have access to your pseudonymised patient data:

- The European Registry statisticians: to validate and analyse the data;
- The European Registry Project Coordination and Monitoring team: to provide support to the centres and national registries on data, software and technical issues;
- The software company: to maintain, protect and improve the database software and to solve software issues.

In addition, the European Registry may visit your centre to verify that the informed consent of the person or his/her legal guardian(s) was obtained in accordance with local and European data protection laws and that the collected data matches the information in the medical records. Only authorised people from the European Registry who have signed a confidentiality agreement with the centre will be given access to the information.

The European Registry's database is hosted on a secure webserver, in a reserved location, in Europe.

9. How long will we process your data for?

Your data will be processed for as long as the European Registry exists. If the European Registry closes, your data will be returned to (*centre name, city*) upon request, or alternatively, destroyed.

You will find more general information on the European Registry website here, and in their Privacy Notice

10. Reconsent

There are 2 instances for when a new Informed Consent form must be signed.

i. When a minor reaches the age at which they can legally self-consent: in most legal systems the validity of consent for a minor that was signed by a parent/parents or legal guardian/s ends when the minor reaches majority age. This means there is a legal and ethical requirement to obtain a new consent from a person who was enrolled as a minor and is now legally old enough to consent, or not, for themself. If the person reaches this age but does not have the capacity to consent, a new consent must be obtained from the legal guardian/s. In many countries the age for self-consent to participate in the (*centre name, city*) Registry and the European Registry is 18, but in some countries it is lower and in some countries it is higher.

ii. A centre must obtain approval to send data to the European Registry from people with CF in their care from their local ethical committee. This means that if a person with CF moves to the care of another centre, a new informed consent must be signed (if that centre also participates in the European Registry).

Informed Consent form

To the person with CF/CFTR-RD or who is CFSPID or Parent(s) / Legal Guardian(s),

Your centre (*name*) in (*city, country*) and the European Cystic Fibrosis Society (ECFS) Patient Registry ("European Registry") collect data from people with CF/CFTR-RD or who are CFSPID in Europe and partnership countries. They do this to measure, survey and compare aspects of CF/CFTR-RD and CFSPID and relevant treatment, to further knowledge of the disease/condition, provide data for epidemiological research, encourage new standards of care and facilitate public health-planning.

Your centre in (*city, country)* and the European Registry invite you to participate in this important research project and ask your **explicit consent** to collect and process your personal data for the above-mentioned purposes. Your centre in (*city, country*) and the ECFS will each act as independent data controllers of your personal data. This means that we need your consent for both registries (European and centre)..

Your participation in the Registry of (*centre name, city*) and the European Registry is voluntary. You have the right to withdraw your consent at any time, without stating a reason, and the right to access your personal data. If you would like to withdraw your consent or exercise your rights you should consult your clinician. The European Registry will not process any of your personal data in the future, but they will maintain the data collected and published before your withdrawal of consent as those data have already been used for scientific research; deleting the data may affect the purpose of the research.
The data in the European Registry is pseudonymised, which means that identification of the person is not possible without additional information. The European Registry is not able to identify you; only your clinician or other authorised medical staff in your centre can do this.

To ensure the quality of the data, the European Registry may visit centres to verify that the informed consent of the person or his/her legal guardian(s) has been obtained in accordance with local and European legislation, and that the collected data matches the information in the patient medical record. Only authorised people from the European Registry, who have signed a confidentiality agreement with the centre, will be given access to the information.

In the future your data may be included in a global registry and used for additional research projects. For scientific purposes personal data may be processed outside Europe. The necessary precautions will be taken to safely process your personal data. If you believe that your rights have been infringed you have the right to lodge a complaint with the supervisory authority. If you wish to do this we advise you to first contact the Operations Manager of the European Registry: coordination@ecfregistry.eu

Data will be processed for as long as it is necessary to carry out the purposes of the European Registry.

Information about the processing of your personal data in your country and by the European Registry is available on the websites (*website address of your registry]*) & https://pr.ecfs.eu/. If you have any questions about the use of your data please contact the Registry of (*centre name*) at *(contact details)* and/or the European Registry at: coordination@ecfregistry.eu.

Please read this document and the information sheet carefully before you decide to participate. If you agree to participate, please complete the information below as indicated.

We thank you for your support.

☐ I agree that my data is used in the CF Registry of (*centre name, city, country*).

☐ I agree that my data is used in the European Cystic Fibrosis Society Patient Registry (ECFSPR).

Name (printed and clear) of the individual or parent / legal guardian (I):

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Signature of the individual (parent / legal guardian): .....

Date: .....

Name (printed and clear) of the the parent / legal guardian (II):

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Signature of the parent / legal guardian (II):: .....

Date: .....

Name (printed and clear) of clinician:

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Signature of the clinician: .....

Date: .....