



The Czech Registry of Cystic Fibrosis

Administered by the **Cystic Fibrosis Center**

Department of Paediatrics, Motol University Hospital, 2nd Faculty of Medicine, Charles University in Prague

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Consent of a patient / a legal representative to processing of personal data
and information on processing of personal data

Dear parents, Madam or Sir,

the Czech Registry of Cystic Fibrosis operates at the Cystic Fibrosis Center in the Motol University Hospital, 2nd Faculty of Medicine, Charles University in Prague. The aim of this registry is to map the incidence of cystic fibrosis and to determine the incidence and character of its' most common complications. The registry was created for scientific purposes only. Data collection was registered and authorized by the Office for Personal Data Protection on 1 July, 2003 under the number 00005954/021.

We would like to ask you to give your doctor a permission to provide the Czech Registry of Cystic Fibrosis with **the following patient data:**

- Name, surname, birth number; **health insurance company.**
- Name and address of the doctor who coordinates your cystic fibrosis treatment.
- Date of CF diagnosis, sweat chlorides values, name of gene mutations that led to cystic fibrosis, ethnic origin. Symptoms that led to the diagnosis.
- General information on the character of your treatment and tests performed, **in case of patients treated with medication that address the underlying cause of the disease (modulators and possibly others), information on the start, the stop of treatment, dosage and side effects will be included;** information on complications of the disease during your therapy, especially the occurrence of bacterial lung infection, diabetes mellitus, intestinal complications, and other necessary information.
- Brief data on lung function tests and a summary of data on height, weight, nutritional status and **smoking.**
- We do not want and do not collect your address or telephone number, only information about the postal code at birth.

Giving or not giving consent **will not affect current or future care for you or your child.** Personal data will be processed only to the extent specified in this Consent, for the purpose described herein and for the period specified below. The collected data will be processed and kept for scientific purposes as follows:

- "Paper" version of data (if any) will be stored in the safe of the Pediatric Clinic of the Motol University Hospital.
- Electronic version of your personal data will be saved on a server operated by the Motol University Hospital, 2nd Faculty of Medicine, Charles University in Prague. Personal data (name, surname and birth number) will be protected by password and encryption, including adequate protection during data transmission. Only employees of the Cystic Fibrosis Center, experts who take care of the relevant server and your doctor who provides the registry with data will have access to your personal data. Deposits for data from previous periods will be kept in the safe.
- Data will be processed in order to determine the incidence of cystic fibrosis in our population, its' complications, process of the disease and basic data on therapy. Your personal data will not appear in any results. Results will be published in professional journals and presented at professional conferences. The ultimate goal of the Registry is to improve care of patients with cystic fibrosis by identifying factors that affect prognosis of the disease.
- Pseudonymized data (i.e. data without first name, surname and birth number) will be sent regularly to the European Cystic Fibrosis Registry, supported by the European Cystic Fibrosis Society. We will provide you with contact information about persons responsible for storing and processing pseudonymized data on request. The objectives of the European Registry are the same as ours: in particular, finding out the number of CF patients in Europe, finding out how they are diagnosed, process of the disease and its' complications. International comparisons provide a unique opportunity to better understand factors that influence course of the disease and occurrence of complications; this will help to analyze the effectiveness of treatment and identify future priorities in care of patients with CF, including the identification of patients who could benefit from participating in research studies. By signing this informed consent, you authorize the Motol University Hospital, 2nd Faculty of Medicine, Charles University in Prague and the Czech Registry of Cystic Fibrosis, to transfer pseudonymized data to the European Cystic Fibrosis Registry.
- For commercial purposes data will only be released if there is a direct benefit to the treatment of CF patients and if all ethical criterias are met. Any use of data from the European Registry is subject to an approval of the Steering Committee composed of selected specialists from across Europe, representatives of other world registries, data processing and protection experts and other experts. In case of data from the Czech Registry of Cystic Fibrosis, the use is subject to approval of the Steering Committee composed of selected specialists from the Czech Republic, representatives of the national registry and a representative of the patient organization.
- **In case of patients treated with medication that address the underlying cause of the disease (CFTR modulators and possibly others), pseudonymized data will be provided to health insurance companies, other eligible entities and contractors monitoring the results of therapy.**
- If any data needs to be added, we will contact only your doctor, not you. If we would like to collect and process data beyond this consent, we will ask you again for your approval through your doctor.

- The data will be kept indefinitely, for the existence of the Cystic Fibrosis Center in Motol University Hospital, the Czech Registry of Cystic Fibrosis or the European Registry of Cystic Fibrosis.
 - The Czech Registry of Cystic Fibrosis is entitled to use your personal data only in accordance with the above-mentioned purpose and for the above-mentioned period.
 - Processing of data will always be performed without providing personal data. Therefore, no name, surname or birth number will ever be given to anyone, all processing will be done under a code not allowing any identification by an unauthorized person.
 - Processing will be done in accordance with relevant legal standards on personal data protection and Regulation 2016/679 of the European Parliament and of the Council (EU), signed on 27 April 2016 on the protection of individuals with regard to processing of personal data and on the free movement of such data and on repealing the Directive 95/46 / EC (general data protection regulation).
 - You have the right to access and correct your data.
 - You have the right to withdraw your consent already given without giving a reason.
 - You have the right to have your personal data deleted. If you decide that your data is to be destroyed, it will be done without undue delay: your name, surname and birth number will be deleted so that it is no longer obvious who it was. We will let you know through your doctor when this happens.
 - You have the right to file a complaint about the method of processing your data with the supervisory authority, which in the Czech Republic is the Office for Personal Data Protection.
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Signature page

Me _____,

Please, check the correct option:

- as a patient with cystic fibrosis
 as a legal representative of a patient with cystic fibrosis

Patient's name _____

Patient's birth number _____

Please, check the option you agree with:

- I agree that the above data may be collected and processed by Czech Registry of Cystic Fibrosis for the purpose of monitoring cystic fibrosis as described above; I have been informed of my rights and I acknowledge that any withdrawal of consent may affect achievement of the purpose for which this consent was given.
 I agree that the above data will be collected and processed by the Czech Registry of Cystic Fibrosis in order to monitor therapy that target the underlying cause of the disease, as described above; I have been informed of my rights and I acknowledge that any withdrawal of consent may affect achievement of the purpose for which this consent was granted.

Date of Signature: _____

Signature: _____

Date of Signature: _____

Signature of a person who obtained the Consent:

(CF doctor/Registry Data Manager) _____