Space for local NHS Trust logo if required. Delete this box if not needed.

UK Cystic Fibrosis Registry
Information for parents/guardians

Your child is being invited to take part in a project to maintain a patient registry (the CF Registry) for people with Cystic Fibrosis (CF). Your child is being invited to take part because he/she has cystic fibrosis. Before you decide whether your child should take part, it is important that you understand why this project is taking place and what it will involve.

Please take time to read the following information carefully and talk to others about it if you want to. You can also ask us if there is anything that you do not understand or if you would like any more information. Take time to decide whether or not you wish your child to take part in this project.

What is the CF Registry?

The CF Registry records and analyses information about the health and treatment of people with Cystic Fibrosis in the UK. It also records the number of people in the UK with CF and where they are. The information is held on a secure and confidential computer database. The CF Registry is paid for by the Cystic Fibrosis Trust.

The purpose of the CF Registry is to improve the health of people with cystic fibrosis. This is done in a number of ways including:

- Helping people with CF and their families understand CF and make informed decisions.
- Giving clinical care teams the evidence they need to improve the quality of care.
- Monitoring the safety and effectiveness of new treatments for cystic fibrosis.
- Providing data for research to find out the best ways to treat cystic fibrosis.

Why have a CF Registry?

CF is a complicated condition that affects a relatively small number of people. By bringing together and analysing the information on all of them, we can understand better the different things that affect people with CF and how different treatments affect them. Doctors can learn from this and provide better care for people with CF in the future.

What information is kept in the CF Registry?

The information kept in the CF Registry is similar to the information that is recorded during your child's usual visits to your CF Centre or Clinic: height, weight, lung function tests, respiratory cultures, x-ray results, and the results of other tests carried out at the hospital. The CF Registry also holds information about the treatments and the drugs given to your child, along with details of any complications that he or she may have. The Registry also records the name of your child's genotype. A genotype is part of a person's genetic makeup, which controls a particular characteristic. In cystic fibrosis, a person's genotype tells us about the severity of their condition, and, in some cases, which treatments will work for them.

Does my child have to take part?

It is up to you and your child whether or not you decide to take part in the CF Registry. If you do decide you would like your child to take part you will be given this information sheet to keep and asked to sign a consent form.

Your child's care will not be affected in any way if you decide not to take part.

What will my child have to do if they take part?

They will not have to do anything. If you decide you would like your child to take part, their care team will enter their information on to the Registry. They will not have to have any additional visits or tests.

How long will you keep my child's data for?

Cystic Fibrosis is a lifelong condition, so the CF Registry aims to keep information indefinitely. This will help us to understand the long-term health of people living with CF and how different treatments work over time.

What are the risks and benefits if my child takes part?

There are no direct risks to your child if you choose for them to take part. There will be no change to their care and they won't have to have any additional tests or hospital visits. Their information will be held securely and confidentiality. You can read more about how we keep information confidential below.

The information we collect within the CF Registry helps doctors and researchers learn more about CF and the best ways to treat it. This benefits everyone with cystic fibrosis both now and in the future.

Can I change my mind later?

Yes, you will be able to withdraw your child from the CF Registry at any time in the future without giving a reason. If you wish to withdraw your consent, inform your child's CF care team. Any personal identifiable information held about your child will be removed from the CF Registry, and no further information will be collected. We will also remove any information about their health and treatments from the database. Their historic, anonymised information cannot be removed from completed or ongoing reports or projects, but it will not used in any new reports or projects in the future.

Your child's care will not be affected in any way if you change your mind and withdraw from the CF Registry.

How is the information collected?

The information is taken from your child's medical notes that are written by the care team whenever your child visits the hospital or when they visit your child at home. If you give consent to participate, we will ask your child's care team to enter the information that has been recorded in their medical notes since their diagnosis into the Registry. We will then ask them to continue to enter information collected in the future. They will enter it into the CF Registry at the hospital and they will be able to use it to follow your child's progress and get an overall picture of everyone with CF at your child's Centre.

What is the information used for?

The information from all the CF Centres and Clinics will be used to get an overall picture of the number of people with CF in the UK, the state of their health and where they are treated. We will then be able to see if there is a difference between the health of people in different hospitals and different regions of the UK. We can then look at the reasons for any differences and use them to make improvements to the care of people with Cystic Fibrosis.

The CF Registry will produce an Annual Report each year that summarises this information and which will be available on the Cystic Fibrosis Trust website (www.cysticfibrosis.org.uk/registryreports). We will also be able to compare the health of people with CF in the UK to the health of people with CF in other countries.

Information from the CF Registry will be used for planning future services for people with CF in the UK. The CF Registry will also be used to identify trends that may not be obvious in one hospital, for example if new infections are emerging, and to identify groups of patients who could take part in research studies and clinical trials. All of these will contribute to improving care for people with Cystic Fibrosis in the future.

Researchers from other hospitals, or universities or companies developing new treatments may apply to access data stored within the CF Registry. Your child's name will never be shared with researchers, we will replace their name with a code number. The technical term for this is pseudonymised data. All applications to access data will be reviewed by the Registry Steering Committee to check that the research will benefit people living with CF. The committee is made up of specialist CF clinicians, representatives of the Cystic Fibrosis Trust and other specialists including people with CF and parent/s of children with CF. Sometimes the research team will be in other countries outside the UK. Research teams in other countries must stick to the rules that the UK uses to keep data safe.

We also use Registry data to monitor the safety of medicines that are made by pharmaceutical companies. This involves the Cystic Fibrosis Trust producing reports based on Registry data that are used by the medicines regulator to assess the safety of cystic fibrosis medicines. The pharmaceutical company also sees these reports. No patient level information, or any information that could identify individuals, is included in these reports. Patient level data, even in anonymised form, is never given to Industry by the UK CF Registry.

We would also like to follow your health status by utilising information collected by other government organisations, such as the Office of National Statistics, and the National Health Service (NHS) Digital hubs in England, Wales, Scotland or Northern Ireland (as appropriate). To obtain this linked information we will need to disclose your date of birth and National Health Service number; these details will be treated in confidence and in accordance with the Data Protection legislation. Linked data sets will be used for research or projects to help improve care for people with cystic fibrosis.

The Cystic Fibrosis Trust is planning to maintain the CF Registry for the foreseeable future and will keep the data indefinitely.

Will my child’s information be confidential?

All the information in the CF Registry is held confidentially. The CF Registry is compliant with Data Protection legislation and has Research Ethics Committee approval. It is managed in accordance with relevant laws and ethical guidelines.

The CF Registry needs to hold information that can identify your child (name, date of birth, and postcode) so that your child’s own hospital can enter the information and use it to monitor your child’s care and to ensure that the information is not recorded more than once. This information is used to generate an anonymous number so that your child cannot be identified when the information from each clinic is brought together to give the overall picture of CF in the UK.

A very small number of experienced staff at the Cystic Fibrosis Trust will also be able to see your child’s personal information. This is to enable the information to be analysed and the system maintained and is in accordance with Data Protection legislation. **People who do not need to know who your child is will not be able to see their name.** Your child’s data will have a code number instead. Information that can identify your child personally will NEVER be given to anyone other than for the purposes outlined above, or published by the CF Registry.

Who has reviewed the project/Registry?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This project was given a favourable ethical opinion by East of England - Cambridge East Research Ethics Committee.

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our website www.cysticfibrosis.org.uk/registry
- by asking a member of your clinical care team
- by sending an email to registry@cysticfibrosis.org.uk or
- by contacting the CF Registry Manager at the Cystic Fibrosis Trust on **020 3795 2180**.

The Data Controller is the Cystic Fibrosis Trust. If you have any questions about the use of your child's data, if you want to make a complaint or if you want your child's information removed from the Registry, please contact the Associate Director of Data & Quality Improvement at the Cystic Fibrosis Trust, 1 Aldgate, London, EC3N 1RE or by sending an email to registry@cysticfibrosis.org.uk.

You can also contact our Data Protection Officer by sending an email to dataprotectionofficer@cysticfibrosis.org.uk

Thank you for taking time to read this information sheet and for considering taking part in the CF Registry. If you have any questions or require any further information please talk to a member of the care team at your CF Centre or Clinic or contact the CF Registry Manager at the Cystic Fibrosis Trust on 020 3795 2180.