

CONSENT FORM

Familial Hypercholesterolaemia Paediatric Register

INFORMATION FOR PARENTS/GUARDIANS

Your child is invited to take part in a register of clinical information about children with FH. We hope to learn more about the long term usefulness of treatments in reducing the risk of heart disease when children grow up, and to improve both the treatments and the care provided. Before you decide, we would like you to understand why there is a need for a register and what it would involve for you. Your doctor or nurse will go through this information with you and answer any questions you have. This should take about 10 minutes. Please, talk to others about this project if you wish.

Why am I being invited to participate?

You are being invited to take part in a project to collect information about children with Familial Hypercholesterolaemia (known as FH) because your child has been diagnosed with this condition. Your child's treatment will not change as a result of participating in this project.

Why do we need a register?

Familial Hypercholesterolaemia (FH) is a condition where the gene which makes a protein that removes cholesterol from the blood does not work properly. This faulty gene is passed down through families. On average, half of the brothers and sisters and children of a person with FH will also have FH. Although there are more than 18,000 children with FH in the UK, up until now, only a small proportion have been identified. The development of cascade* or family-relative testing means that more children are being diagnosed with FH and offered advice and treatment which will lower their risk of heart disease in the future.

This Register will make it possible to collect information about FH treatment from children all over the UK to help study the condition and to see which treatments work best. (See below under *How will the information be used?* for more details.)

* Cascade testing is the phrase used to describe the way relatives of a person with FH are tested to see if they also have the faulty gene so that family members with FH can also be offered advice and treatment to lower their risk of heart disease.

What are the benefits?

Your child may not benefit directly from the project in the near future. There is no financial benefit to participating in this project. The information collected will be used for research. We will learn more about the long term effectiveness of FH treatment on lowering the risk of future heart disease and improving both the treatments and the care provided.

How will information be collected?

In clinics that see children with FH, if you have consented, a member of your medical team will enrol your child and enter some key pieces of information about their FH directly on the Register. NHS site will collect information about your child for this research study from your child's medical records. This information will include their name, NHS and hospital numbers, date of birth, post code, ethnicity, gender and health information, which is regarded as a special category of information. RCP will use this information as part of a register to collect information about all children in the United Kingdom who were diagnosed with FH under the age of 18 years. The register will collect information on what treatments are used and their outcomes. Each time your child comes to the clinic this information will be updated.

What information will be collected?

The aim is to collect information about all children in the United Kingdom who were diagnosed with FH under the age of 18 years. It will collect information on what treatments are used and whether there have been any problems with them. It will also collect information on such things as growth, age of reaching puberty, and patterns of taking medication. A full list of the information being collected is available on request from the Project Manager whose details are listed at the end of this document.

What am I being asked to do?

You are being asked to give permission for your child's medical team to put information about your child into the Register. NHS site will use your child's name, your child's NHS and hospital numbers, post code, date of birth, ethnicity and gender and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Individuals from RCP and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study. NHS site will pass these details to RCP along with the information collected from your child's medical records. The only people in RCP who will have access to information that identifies your child will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your or your child's name, their NHS number or hospital numbers or contact details.

RCP will keep identifiable information about you from this study until they turn 18 and for as long as possible afterwards.

In addition, you are being asked to allow us to set up an electronic flag with the Health and Social Care Information Centre so that the information is automatically updated if your circumstances change (for example if your child emigrates). You are not giving permission for anything else. There will be no change to your child's treatment and no additional tests or procedures as a result of participating.

How will information be kept confidential?

The Register is based at the [Royal College of Physicians](#) which will be responsible for the organisation of the project. Royal College of Physicians (RCP) is the sponsor for this study based in the United Kingdom. RCP will be using information from your child's medical records in order to undertake this study and will act as the data controller for this study. This means that RCP are responsible for looking after your child's information and using it properly. RCP will keep identifiable information about your child until they become adults and for as long as possible afterwards

Your rights to access, change or move your child's information are limited, as RCP need to manage your child's information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw your child from the study, RCP will keep the information about them that they

have already obtained. To safeguard your child's rights, RCP will use the minimum personally-identifiable information possible.

There are a number of rigorous procedures in place to protect the confidentiality of participants. These have been approved by the Royal College of Physicians and are available on request. All information is stored in a secure area on the Royal College of Physicians' server (computer).

No one except your child's medical team and a few people working on the project at the Royal College of Physicians, who have all signed a confidentiality agreement, will be able to see information which would identify your child. When information is provided to others (see next question) it will be anonymous, that is, *no information provided to anyone will contain any details which could identify your child or your family.*

Your child's information could be used for research in any aspect of health or care, and could be combined with information about them from other sources held by researchers, the NHS or government.

Where this information could identify your child, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you and your child about future opportunities to participate in research. It will not be used to make decisions about future services available to you or your child, such as insurance.

Where there is a risk that your child can be identified their data will only be used in research that has been independently reviewed by an ethics committee.

You can find out more about how RCP use your information [at <https://audit.rcplondon.ac.uk/paedfh/page.aspx?pc=homepage> and by contacting Dr Uma Ramaswami, Clinical Study Lead at uma.ramaswami@nhs.net

How will the information be used?

Anonymous information will be sent regularly to doctors treating people on the Register. This will help them to compare how they are treating their patients with other doctors and to improve treatments (clinical audit), as well as help to spot if anything unusual is occurring.

If someone else wishes to use the anonymous information to do research, they will need to apply to the Steering Group (a group of experts and patients who oversee the Register) for permission. The Steering Group will only approve research that may benefit people with FH and that is technically sound. If approved they will only be given anonymous information.

Under no circumstances will insurance companies or employers be given any individual's information, nor will we allow access to the police, relatives or lawyers, unless required to do so by the courts.

How long will the information be collected and for how long will it be stored?

We plan to continue the follow up of the children on the Register until they become adults and for as long as possible afterwards. This is so we can learn about the effects of early treatment on lowering the risk of heart disease in adulthood.

What happens when my child becomes an adult?

When your child is 18 years old, which is the age when children are legally able to make decisions about their health, they will be asked for consent to continue to participate. This will be recorded with their signature using a new consent form. Should they refuse, no more information will be collected and, should they wish it, all of their information on the Register will be deleted.

What happens if at some time in the future I or my child do not want to participate anymore?

You or your child can at any time withdraw from the Register and no further information will be collected. Should you or your child wish it, all of their information on the Register will be deleted.

What happens next?

Please take the time to read this information carefully, and discuss it with your family if you wish. Also, please discuss it with the doctor who is giving you this form, particularly if anything is not clear. If you would like more information please contact the Project Manager fh@rcplondon.ac.uk. If you agree to take part, you will be asked to sign a Consent Form on behalf of your child. This form will be kept on record. Following your consent, the doctor will start to put information into the Register.

Who do I contact if I have any concerns about the project?

For general enquiries please contact the Project Manager (fh@rcplondon.ac.uk)

If you have concerns, please contact either:

Rhona Buckingham
Manager,
Clinical Effectiveness and Evaluation Unit
Clinical Standards Department
Royal College of Physicians
11 St Andrews Place
London NW1 4LE
020 3075 1649
Rhona.Buckingham@rcplondon.ac.uk

HEART UK - The Cholesterol Charity
7 North Road
Maidenhead
Berkshire
SL6 1PE
Helpline: 0845 450 5988
Email: ask@heartuk.org.uk

CONSENT FORM

Familial Hypercholesterolaemia (FH) Paediatric Register

Parent/Guardian Consent of children under 18 years

Name of Consultant _____

Participant First Name: _____ Last Name _____

Participant identifier: _____

The purpose of FH Register is to collect information which will act as a resource for future research on FH and the effects of treatments on children and young people.

This form is asking for your permission for clinical information about your child to be collected and stored for future research. Please tick the box on the right if you agree.

1. I have read and understand the Participant Information and Consent Form: Patients/Guardians_v5.0_23 September 2018 and have had the opportunity to ask questions.
2. I understand that I can choose whether or not my child will participate without it affecting his/her care.
3. I understand that I am giving consent on behalf of my child up until s/he is 18 years of age at which time s/he will be asked for consent directly.
4. I understand that I can withdraw at any time without giving any reason and all information will be deleted if this is requested.
5. I give permission for access to the health information related to FH of my child, and for long-term storage and use of this for the purposes the Register.
6. I give permission for the Health and Social Care Information Centre to flag my child's record.
7. I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from Royal College of Physicians, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my records.
8. I understand that none of my child's results will be given to any one in a form which could identify my child or my family. If any findings are published in a scientific journal all information will be as anonymous statistics.

Name of person giving consent

SIGNATURE _____ First Name _____ Last Name _____

DATE _____

Relationship (please circle appropriate answer)

Parent Guardian

Name of person obtaining consent

SIGNATURE _____ First Name _____ Last Name _____

DATE _____

Job title _____