Royal College of Physicians
Setting higher medical standards

ASSENT FORM
Familial Hypercholesterolaemia Paediatric Register
INFORMATION FOR PATIENTS Aged 16-18 years

You are invited to take part in a register of clinical information about children and young people with FH. We hope to learn more about the long term usefulness of treatments on 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 and young people with Familial Hypercholesterolaemia (known as FH) because you have been diagnosed with this condition. Your 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 what 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?

You 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 to improving both the treatments and the care provided.

How will information be collected?

If you have given your assent, a member of your medical team will sign you up and enter some key pieces of information about your FH directly into the Register. The NHS site will collect information about you for this research study from your medical records. This information will include your name, NHS and hospital numbers, date of birth, post code, ethnicity, gender and health information, which is regarded as a special category of information. The Royal College of Physicians (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 you come to the clinic this information will be updated.

What information will be collected?

The Register plans 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 medical team to put information about you into the Register.

The NHS site will use your name, your NHS and hospital numbers, post code, date of birth, ethnicity and gender and ensure that relevant information about the study is recorded for your care and to oversee the quality of the study. Individuals from RCP and regulatory organisations may look at your 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 medical records. The only people in RCP who will have access to information that identifies you 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 name, you NHS 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 you emigrate). You are not giving permission for anything else. There will be no change to your treatment and no additional tests or procedures as a result of participating.

How will information be kept confidential?

The information in the Register is being held in an electronic database at the Royal College of Physicians (RCP), based in the United Kingdom, which will be responsible for the organisation of the project. RCP is the sponsor for this study based in the United Kingdom. RCP will be using information from your 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 information and using it properly. RCP will keep identifiable information about you as long as possible.

Your rights to access, change or move your information are limited, as RCP need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw from the study, RCP will keep the information about you that they have already obtained. To safeguard your 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 medical team at your hospital 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 you. When information is provided to others (see next question) it will be anonymous, that is, n*o information provided to anyone will contain any details which could identify you or your family.*

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

Where this information could identify you, 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 about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified, your 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 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.

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. The RCP will keep identifiable information about you until you have at least reached the age of 18.

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What happens when a person becomes eighteen?

If you are 16-18 years old, you are being asked to read the information and agree to take part. Your parent or guardian will also be given this information and asked to consent to your participation. If you do not agree to take part in the study, you will not be enrolled in the study even if your parent or guardian has consented.

When you are 18, which is the age when you are legally able to make decisions about your health, you will be asked again for your consent. Should you refuse, no more information will be collected and, should you wish, all of the information held on the register will be deleted.

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

You can at any time withdraw from the Register and no further information will be collected. Should you wish it, all of your 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 this form. Your parent or guardian will also be asked to sign a consent form. This form will be kept on record. Following your agreement, 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

ASSENT FORM

Familial Hypercholesterolaemia (FH) Paediatric Register

Assent of patients 16-18 years

I agree to allow information about my condition and treatment to be put into the Register.

☐ Yes ☐ No

Patient's Name (printed)_____ Patient's Age _____

If you sign this form, you agree to allow us to put some information about you on our computer for research studies:

_____ _____

Signature of Patient **Date**

Person obtaining assent

SIGNATURE_____ First Name_____ Last Name _____

Job title _____ Date _____

FH Paediatric Register
fh@rcplondon.ac.uk