

[LOGO]

National Familial Hypercholesterolemia Registry

INFORMATION FOR PATIENTS

Introduction

You are invited to contribute your health information to a database of patients receiving medical treatment for Familial Hypercholesterolemia (FH) at [SITE NAME].

It is hoped that research on this database will help researchers to better understand the nature of Familial Hypercholesterolemia and assist in developing future clinical research. The National FH Registry is being established and supported financially by the FH Australasia Network (Australian Atherosclerosis Society). The research will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research, 2007.

Contributing to the Registry

If you agree to participate in this Registry, you will not be required to do anything other than sign the Patient Consent Form. Relevant information will then be obtained from your medical record and stored in the database. The Registry will record information including name, address, date of birth, email and contact telephone numbers as well as treating doctor's name, address, telephone number and email. Clinical information such as family history of FH, history of cardiovascular disease and cardiovascular disease risk factors, treatment and blood lipid levels will be provided by your treating doctor and recorded. If genetic testing has been done, the affiliated laboratory services will be asked to provide details of the results. This information will be entered by your clinic co-ordinator or treating doctor when you are registered onto the Registry. Ongoing clinical information will also be recorded. Your information will be kept in the Registry for 60 years.

In the Registry your health information will be identified with a number to protect your privacy. Your name will be recorded in connection with this number, but information about you will only be linked to your number. The information will always be treated confidentially, and only the database custodian, his/her assistants and authorised researchers will have access to it. The Registry was created using the Rare Disease Registry Framework (RDRF), which was developed by the Centre for Comparative Genomics at Murdoch University. All confidential information shall be encrypted and stored securely in accordance with the Privacy Act 1988 (Cth) and the Australian Privacy Principles. We will use Amazon Web Services (AWS) cloud infrastructure located in Australia and all patient data collected in the Registry will remain in Australia.

The results of research conducted using the Registry may be presented at a conference or in a scientific publication, but individual patients will not be identifiable in such a presentation. Any research conducted using the Registry will have been approved by a Human Research Ethics Committee (HREC).

Benefits

While we intend this database to be used to further medical knowledge and to improve treatment of Familial Hypercholesterolemia in the future, it may not be of direct benefit to you.

Costs

Contributing to this Registry will not cost you anything, nor will you be paid.

Voluntary Participation

Contributing to this database is entirely voluntary. You do not have to do so. If you do, you can withdraw your health information at any time without having to give a reason. There are no laws that require this particular information to be collected. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you. There are no consequences to you and your family if all or part of the information is not provided.

Further Information

When you have read this information, your treating doctor at [SITE NAME] will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact the Clinical contact persons below. For more information, please refer to the Terms of Reference of the FH Registry Charter provided by your treating doctor.

This information sheet is for you to keep.

Ethics Approval and Complaints

The establishment of this Registry has been approved by the [ETHICS COMMITTEE NAME].

[SITE CONTACT DETAILS]

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

[ETHICS COMMITTEE CONTACT DETAILS]

National Familial Hypercholesterolemia Registry

PATIENT CONSENT FORM

I,.....[name]

of.....[address]

have read and understood the Information for Patients on the above named Registry

and have discussed it with.....

I have been made aware of the procedures involved.

I understand that contributing to the Registry will allow the researchers to have access to my medical record, and I agree to this.

I freely choose to contribute to the Registry and understand that I can withdraw my health information at any time.

I also understand that the Registry is strictly confidential.

I hereby agree to contribute my health information to this Registry.

Name of Participant: _____

Signed: _____

Dated: _____

- I would like to be contacted about clinical trials and other studies in which I can participate Yes / No
- I would like to be kept informed of new information and research in Familial Hypercholesterolemia Yes / No

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Signed: _____

Dated: _____

(Investigator)

National Familial Hypercholesterolemia Registry

PATIENT REGISTRATION DETAILS

First name: _____

Family name: _____

Date of Birth (dd/mm/yyyy) _____

Address: _____

Postcode _____

Telephone: _____

Mobile phone: _____

Email: _____

If you would like to register directly with the Registry please provide the name of your doctor below giving us permission to contact your doctor directly if we require further information to complete your registration

You have my permission to contact my doctor for my personal details:

Doctors Name: _____

Clinic / Medical Practice Address: _____

Clinic / Medical Practice Telephone: _____

Specialist Name: _____