Appendix 4. Positive Results Package

fH Australasia Network
everyone deserves
a better chance

Familial Hypercholesterolaemia Clinical Support Service
Royal Prince Alfred Hospital

LIPID SPECIALIST **GENETIC COUNSELLORS** **RESEARCH NURSES**

Dear Dr [Name],

RE: [patient name] DOB:

As you are aware, results of the familial hypercholesterolaemia (FH) genetic testing that you ordered for [patient name] recently became available.

Their result shows that they **have inherited the gene change in their family.** This result confirms that they have the condition FH, so it is important they monitor and manage their cholesterol levels with your help.

We have enclosed a pre-written letter that can be given to your patient regarding the outcome of their genetic testing. We encourage you to also provide them with a copy of their genetic test report.

Management guidelines for individuals with FH are available at HealthPathways:
https://sydney.communityhealthpathways.org/

Additional information can be found in the FH Cascade Screening information (enclosed).

We have also enclosed a letter for your patient to pass onto any of their relatives who may now need genetic testing for the FH gene change found in their family. Please note that first-degree relatives (parents, siblings, children) have a 50% of also having FH and second-degree relatives (grandparents, grandchildren, half siblings, aunt/uncle, niece/nephew) have a 25% chance of also having FH.

National FH Registry
Your patient is invited to contribute their health information to a national database of patients receiving medical treatment for FH throughout Australia. Further participant information for the patient is enclosed. If your patient is interested in participating in this Registry they will only need to complete the consent form and return it to [clinic email address]

If you or your patient have any additional questions, you are welcome to contact one of our genetic counsellors on [phone number] or email [address].

Yours sincerely,

The FH Clinical Support Service

Enc: Patient FH Results Letter
Family Letter
FH Registry Patient Information and Consent Form

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Familial Hypercholesterolaemia Clinical Support Service
Royal Prince Alfred Hospital

LIPID SPECIALIST **GENETIC COUNSELLORS** **RESEARCH NURSES**

Dear [Patient],

You underwent genetic testing for a gene change identified in your family that causes Familial Hypercholesterolaemia (FH). **Your result showed that you have inherited this gene change (XXXX).** This result confirms that you have the condition FH. **Please ensure you arrange an appointment with your doctor to discuss these results and your ongoing management.**

Additional information about FH can be found at the FH Australasia Network:
https://www.athero.org.au/fh/patients/what-is-fh/

We have enclosed a letter for you to pass onto any relatives who may now need genetic testing for the FH gene change found in your family. Please note that first-degree relatives (parents, siblings, children) have a 50% of also having FH and second-degree relatives (grandparents, grandchildren, half siblings, aunt/uncle, niece/nephew) have a 25% chance of also having FH.

National FH Registry
You are also invited to contribute your health information to a national database of patients receiving medical treatment for Familial Hypercholesterolemia (FH) throughout Australia. Further participant information is enclosed. If you are interested in participating in this registry you will need to complete the consent form and return it to [clinic email address]

If you have any additional questions, you are welcome to contact one of our genetic counsellors on [phone number] or email [address]

Yours sincerely,

The FH Clinical Support Service

Enc: FH Registry Patient Information and Consent Form
Family information letter
Genetic Test Result

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Familial Hypercholesterolaemia Clinical Support Service
Royal Prince Alfred Hospital

LIPID SPECIALIST **GENETIC COUNSELLORS** **RESEARCH NURSES**

Genetic File:

___/___/___

Dear family member,

A relative of yours has been diagnosed with a genetic condition called familial hypercholesterolaemia (FH). This condition causes high cholesterol and increases the risk of getting heart disease at a young age.

FH runs in families so there is a risk that you also have FH. Fortunately, therapy is safe, easy, and effective at lowering the risk of heart disease.

Your local GP can help to check if you have FH. This can be done through:

1) LDL-cholesterol check (blood sample), or
2) Genetic testing (blood or saliva sample)

We urge **all relatives** of a person with FH to have an LDL-cholesterol check. Genetic testing for FH is voluntary and Medicare rebated for at-risk relatives. Your GP can arrange testing for the specific FH genetic variant in the _______________ **gene,** identified in your family. They will need the reference **laboratory ID number MD -**______________________.

Please provide your contact details by scanning the QR code below. Someone from the RPA Hospital Vascular Health Clinic will be in touch to provide information to you and your GP to help with arranging this testing:

QR
CODE

Or, click on the link: http://redcap.link

You are also welcome to talk with one of our genetic counsellors on (xx) xxx xxxx or email [clinic email]

Yours sincerely,
The FH Clinical Support Service

Useful information on FH:

- Australian Atherosclerosis Society what is FH - https://www.athero.org.au/fh/patients/what-is-fh/
- World Heart Federation what is FH video - https://youtu.be/4YwdFSN3xpA

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National Familial Hypercholesterolemia Registry

INFORMATION FOR PATIENTS

Introduction

You are invited to contribute your health information to a national database of patients receiving medical treatment for Familial Hypercholesterolemia (FH) throughout Australia. 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. Over 1500 people are currently enrolled in the FH Registry.

The National FH Registry is overseen and supported financially by the FH Australasia Network (Australian Atherosclerosis Society).

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 demographic 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 lipid concentrations 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. 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, its staff and authorised researchers will have access to it. All confidential information will 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. Research data may be shared locally and internationally with other research collaborators in future, however ethics approval will be sought prior to sharing.

Benefits

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

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Risks

There is minimal risk in taking part in the Registry. The Registry includes questions that may be considered sensitive and some participants may feel uncomfortable answering. You do not have to share any information you do not want to. Another unlikely risk is potential breaches in the computer system. In the event that there is a breach in the Registry's computer system all participants will be notified.

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 by contacting your treating doctor, or the local Registry co-ordinator at [email], or the National Co-ordinator at fh@athero.org.au. 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.

Further Information

When you have read this information, the FH Clinical Support Service at {insert hospital 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 genetic counsellor on {insert phone number}.

For more information, please refer to the Terms of Reference of the FH Registry Charter provided by your treating doctor and/or please refer to the Australian Familial Hypercholesterolemia Registry website (https://fhregistry-international.com/).

This information sheet is for you to keep.

Ethics Approval and Complaints

The establishment of this Registry has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about it should contact the Executive Officer on 02 9515 6766 and quote protocol number X14-0135.

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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 consent to the future use of any data I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval.

I consent for other research collaborators to use any data I provide for future research purposes. I understand that before they can use my data, they must seek additional ethics approval.

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 would like to be contacted about clinical trials[1] and other studies in which I can participate YES/NO
- I would like to be kept informed of new information and research in FH YES/NO
- I would like to be emailed a copy of the study results YES/NO
  - (if YES) my email address is: …………………………………………………..

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

NAME: ....

SIGNATURE: .... **DATE:** ………...........................

NAME OF WITNESS: ....

SIGNATURE OF WITNESS: .... **DATE:** ………..........................

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[1] **Please note** that if we inform your doctor about the existence of a trial, this does not imply that we endorse it. In order to participate in any trial, you and your child will need to discuss it with your family and your doctor and will be required to fill out a separate informed consent form that relates to that specific trial.

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PARTICIPANT 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: ______________________________

FH Registry MASTER Consent Form, Version 3, 10/06/2020
RPAH SITE SPECIFIC FH Registry Consent Form, Version 3, 10/06/2020