

Haemoglobinopathy Registry – Patient Information Brochure

Monash Medical Centre

Genetic disorders of haemoglobin (haemoglobinopathies) are important inherited conditions. These disorders include α -thalassaemia, β -thalassaemia, sickle cell disease and haemoglobin H disease. These conditions vary greatly in their severity, depending on the specific genetic variant involved, but many affected people require blood transfusions and iron chelation therapy from an early age.

Monash University's Department of Epidemiology and Preventive Medicine has established a database called the Haemoglobinopathy Registry, to gather information from patients with a diagnosed haemoglobinopathy.

Why is this information needed?

Although clinical management of haemoglobinopathies is continuously improving, much remains unknown about these disorders. The data gathered through the Registry will answer important questions such as:

- Approximately how many people in Australia are affected by haemoglobinopathies?
- What medical management strategies work best for people with haemoglobinopathies?
- What are the long-term outcomes for patients?
- How can Australian health services provide better care for people with haemoglobinopathies, now and in the future?

What information is collected?

Information about people being treated for a haemoglobinopathy will be forwarded to the Registry by their treating clinician or by an authorised data collector for that hospital.

This information will mostly be gathered from your existing medical record, however, there are a few additional questions that your clinician might ask you directly.

The information will be limited to:

- Your name, date of birth, Medicare number, hospital record number and doctor, so we can track the progress of your health and treatment over time
- Your ethnic background, as haemoglobinopathies are genetic disorders and occur with different frequencies in different communities
- Your physical characteristics such as height, weight and gender
- Your symptoms and diagnostic test results, such as blood tests and scans
- The type of treatment that you receive, your response to treatment and any complications of the illness or treatment
- Your access to health care services
- How your condition may affect your quality of life

How is my privacy protected?

The Haemoglobinopathy Registry has been designed in accordance with the strictest privacy principles, including State and Commonwealth privacy laws, and has been reviewed by independent ethics committees, including the committee at your hospital.

The information collected will:

- Comply with all privacy legislation
- Not be released in a way which could potentially identify a specific person, unless
 - That person is receiving care from two or more hospitals contributing to the Registry, in which case information related to diagnosis and treatment received may be shared between the sites, or
 - in the very rare case of a court order
- Be stored securely, and indefinitely, at Monash University, with access to identifying data restricted only to approved clinicians at your hospital, approved data collectors for your hospital, and a single data auditor at Monash University's Transfusion Research Unit, each of whom is committed to maintaining confidentiality

Researchers will use your information to determine aggregate (grouped) statistics. Identifying information, such as name, date of birth and Medicare number is of no interest to researchers and is only recorded so that we do not duplicate your record if you move from one hospital to another, to facilitate data audit and to allow possible future linkage with other data sets, for example, hospital laboratory records.

Any future additional research undertaken using registry data will require researchers to obtain approval by the appropriate hospital ethics committee and from the Haemoglobinopathy Registry steering committee. If approval is given, the researchers will have access to non-identifiable data only.

In consenting to having this information collected, you will be agreeing to have this information used for research which aims to investigate issues relating to the care of patients with haemoglobinopathies.

Participants can access the data stored about them in the Haemoglobinopathy Registry by contacting the project officer.

How can I participate or decline to participate?

You are not obliged to participate in the Haemoglobinopathy Registry project. If you do not wish to participate, this will not impact on your care in any way.

If you wish to participate, *do nothing*. Unless you specifically tell your doctor/nurse or registry staff at Monash University within 2 weeks of receiving this brochure that you do not wish to participate, your information will be included in the registry. You can withdraw from the registry at any time by contacting registry staff.

If a child participant reaches the age of 18 while the registry is still collecting information, a letter will be sent from the treating hospital to the young adult to inform them of their participation and that they can opt out at any time. A patient brochure with opt-out information will be included with that letter.

Questions? Concerns?

If you would like more information, have any concerns about the way this project is being conducted, or wish to withdraw from the study at any time, please contact the registry project manager listed below, the project leader at your hospital, or the your hospital's research governance office.

Haemoglobinopathy Registry Project Manager Department of Epidemiology and Preventive Medicine, Monash University, Australia Toll Free Phone: 1800 811 326 Email: hbr@monash.edu	Project Leader for Monash Medical Centre: Dr Zane Kaplan Department of Haematology Phone: (03) 9544 6448 Email: zane.kaplan@monashhealth.org
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The conduct of this study at the Monash Medical Centre has been approved by the Monash Health Human Research Ethics Committee. Any person with concerns or complains about the conduct of this study may also contact the Research Governance Officer on (03) 9594 4611 or email them at research@monashhealth.org and quote reference number 13372A.

DECLINE TO PARTICIPATE

If you wish to be part of the Haemoglobinopathy Registry, there is no need to do anything. Your (or your child’s) details will be added to the database soon. If you later change your mind, you can contact us in one of the ways listed below to opt out.

If you have decided you DO NOT wish to be part of the Haemoglobinopathy Registry, please do one of the following:

1. Call the Registry Officer at Monash University on 1800 811 326 and explain that you wish to opt out of the Haemoglobinopathy Registry – you will need to give us your name, date of birth and the name of the hospital treating you (or the same details for a child, if you are declining on behalf of a child).
2. Email hbr@monash.edu with the same information as for option 1.
3. Fill in the form below and post to:

HbR Project Officer
Transfusion Research Unit, Department of Epidemiology and Preventive Medicine,
Monash University
Level 6, 99 Commercial Rd
Melbourne VIC 3004

I have read the Haemoglobinopathy Registry information brochure and I have decided that I **DO NOT** wish to have my details included in this research project.

Patient first name:

Patient surname:

Patient Date of Birth:

Name of treating hospital: XXX Hospital

Signature: Tick here if you are a parent/guardian declining and signing on behalf of child patient

Date:

If you received this brochure **more than 2 weeks ago**, some of your information may have already been entered into the registry. If this is the case, we should:

- Leave what has been collected already, but not collect any more information
- Delete all your medical information and not collect any more information
- N/A - I received this brochure less than 2 weeks ago

