

Participant Information

Non-Interventional Study - Parent / Legal Guardian consenting on behalf of child

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| Title | Map-HD Registry |
| Short Title | Map-HD Registry |
| Protocol Number | HDNA-Registry-0001.0 |
| Project Sponsor | Monash University |
| Coordinating Investigator/ Principal Investigator | Professor Julie Stout email Julie.Stout@Monash.edu phone (03)9905-3987 |
| Associate Investigator | Dr Yifat Glikmann-Johnston email Yifat.Glikmann-Johnston@Monash.edu phone (03)9902-0238 |
| Location | Monash University |
| Registry Type | Self-Report Registry |

1. Introduction

The Map-HD Registry collects information from people in Australia affected by Huntington's disease (HD). This includes people with HD and their family members and carers.

Please read this information before deciding to register a child you care for. Feel free to discuss it with others, such as your family or doctors. Make sure you understand it. You are welcome to contact the registry team to ask questions. Their email addresses and phone numbers are in the table above this section.

Participation in the Map-HD Registry is voluntary. There will be no effect on the child's care and services if they take part. Participation is free of cost.

This consent form enables you to consent on behalf of a child in your care whom you are assisting to participate in the registry. Only use when the person you are registering is unable to provide informed consent themselves (being a minor under 18 years of age).

Parents/legal guardians who believe that the child is able to understand what it means to participate in the registry are encouraged to gain assent from the child. Assent is an indication from the child that they understand and wish to participate.

Parents/legal guardians who believe that the child is unable to understand what it means to participate in the registry are not required to gain the **assent** of the child.

Do not provide consent and register a child who has the cognitive maturity to understand, if they are not aware that they are at risk for HD.

The consent form follows this information. The child you are consenting for is referred to as the 'participant'.

You can download a copy of this information from the Huntington's Disease Network of Australia (HDNA) website at hdna.com.au. You may log in to the registry at any time to view your consent and any information you provide.

2. What is the purpose of the Map-HD Registry?

To enable research that fosters the best quality of life for all people in Australia affected by HD.

The registry is the first-ever collection of data from people across Australia aimed at:

- Finding people that may benefit from new services and treatments
- Increasing the efficiency of HD research in Australia
- Connecting people to research and clinical trial opportunities
- Generating new knowledge about HD to help find treatments and improve care

3. What information do I need to provide about the participant to join the Map-HD Registry?

For the participant to take part in the Map-HD Registry, you first need to provide consent. You then answer questions about them in the Map-HD Registry portal.

Some questions are **REQUIRED**. They take about 10 minutes to complete:

- The participant's first and last name
- The participant's date of birth
- The participant's post code
- How you prefer us to contact you in future (via text, email, phone call or post)
- The participant's sex and gender
- Whether the participant has had a blood test for the HD gene
- Whether the participant has been diagnosed with HD

Other questions are **OPTIONAL**. They take about 20 minutes to complete:

- The participant's CAG-expansion (or repeat number) if they have had the HD genetic test
- Which HD specialist clinicians or services the participant uses, if any
- How far the participant travels to clinical appointments
- Whether the participant has accessed the National Disability Insurance Scheme (NDIS)

Additional options: If you agree

- We will provide the participant's contact details (which may be your contact details) to an HD State Association.

- We will use the participant's first and last name, address, date of birth, sex and a data linkage ID for linking to other datasets.
- We may contact you about OPTIONAL research or clinical trial opportunities, HD related services or activities.

4. What steps do I need to take to join the Map-HD Registry?

To join the registry:

Step 1: Create an account by entering a username and password. Your account is stored on a secure and private Map-HD Registry portal.

Use your account whenever you log in. You can register more than one person with your account. For example, using your account, you may register a child you care for and yourself. Each person registered has their own consent. The registry separates each person's information. Each person's record is their profile.

Step 2: Read this Participant Information or watch the video, if available. Make sure you understand the information. If you have any questions, get them answered before continuing.

Step 3: Read the Consent Agreement.

Step 4: Read the OPTIONAL Consent Agreement that follows. Tick the boxes if you agree to the statements.

Step 5: Where you see 'Declaration by Parent / Legal Guardian', fill in your name and the date. By filling in your name you are consenting to participate.

Step 6: The registry gives you questions to complete about the participant. You can ask someone you trust to assist you in completing the questions.

You can look at a summary of the responses by going to the summary page.

5. Can I stop before answering all the questions and complete some questions later?

Yes. You may log out and back in at any time.

When answering questions, each page saves when you click the 'Save and Continue' button. If you leave a page before clicking 'Save and Continue' that information will not save.

6. What will happen with the data I provide?

The Map-HD Registry is housed at Monash University, in Victoria, on secured computer systems.

Monash University will use the participant's information you provide for the purposes described in this document.

No records will be released with identifying information EXCEPT if you provide clear permission to do so.

Sharing of de-identified data from the Map-HD Registry

Before sharing data, personal information is removed. For example, the participant's name and address are removed. All information that could identify a particular person is removed. The data without personal information is called **de-identified data**. De-identification protects the identity of people included in the registry.

We plan to share data with researchers, clinicians, HD State Associations, Government, and industry. To obtain data, a formal request must be made to the Map-HD Steering Committee. The purpose of sharing of data is to help generate new understanding of HD and to help find treatments.

Findings will be published in journals. Researchers may describe the findings in talks in Australia and overseas. We will share findings in newsletters, social media and other media. We will describe the de-identified data.

OPTIONAL: Sharing the participant's contact details (which may be your contact details) with a selected HD State Association

You can choose to share the participant's name and contact details with an HD State Association. HD State Associations provide supports for people with HD, their families and carers.

OPTIONAL: Data Linkage

We want to create a complete picture of HD in Australia. To make a complete picture, we will link the Map-HD Registry dataset with other datasets which contain information about the participant. Some examples are:

- Medicare (MBS)
- Pharmaceutical Benefits Scheme (PBS)
- National Disability Insurance Scheme (NDIS)
- Australian Institute of Health and Welfare (AIHW), and
- Clinical and research data linked to the people who participate in the registry.

Data linkage processes may require additional informed consent. If needed, someone from the Map-HD Registry team will contact you.

Some people in the Map-HD Registry are in the Enroll-HD study. Enroll-HD is a worldwide study for HD families. It is only available at a few centres in Australia. Specific consent is needed for data linkage with Enroll-HD. If you consent to the participant's registry data being linked to

Enroll-HD data, we will contact their Enroll-HD site. The details we will share with their Enroll-HD site are the participant's:

- first name
- last name
- date of birth
- address
- sex
- data linkage ID

This information enables the CHDI Foundation to link records between the Map-HD Registry and the Enroll-HD study. The CHDI Foundation is the organisation that funds the Enroll-HD study.

Participation in data linkage is optional. To participate in data linkage, you must tick boxes in the Data Linkage section in the consent form.

7. What are the possible benefits of taking part in the Map-HD Registry?

- Finding out about opportunities for accessing clinical services, research, treatments, and HD events.
- Creating more knowledge about HD in Australia. More knowledge may speed up the approval of new services and treatments.
- Improved knowledge about HD may increase funding from Government or charities.
- Locations of HD services may be improved to better match where people live.

We cannot guarantee that you or the participant will benefit from participating in the Map-HD Registry.

8. What are the possible risks and disadvantages of taking part?

We do not expect risks or disadvantages from taking part. We have detailed policies and procedures to maintain the privacy and security of participant data. You can read the Terms and Conditions on the registry website. You can request additional details by contacting the registry team at info@hdna.com.au.

9. Can I withdraw the participant from the Map-HD Registry?

Yes, you can withdraw the participant from the registry at any time. To withdraw, delete their user profile. You may notify a member of the research team before you withdraw the participant, or to assist you.

If you withdraw the participant, we will not collect additional information from you. We save the information you provided so far. Reports include the participant's saved information as de-identified data. Tell the researchers if you do not want the participant's data included.

10. When will the registry close? Could it stop without warning?

There is no planned end date for the registry. The registry could be stopped if:

- No funding is available to maintain it, or
- it no longer holds value for the Australian HD community.

If the registry closes, we will archive all data. The data will be stored securely at Monash University. We plan to continue sharing de-identified data for approved uses.

You have the right to request access to the information collected and stored by the research team about the participant. You have the right to request that any incorrect information is corrected.

11. What should I do if I wish to make a complaint?

If you have complaints about the registry or if you have questions, contact:

Monash Health Human Research Ethics Committee
Executive Officer
Phone: 03 9594 4611
Email: research@monashhealth.org

If taking part causes you or the participant to feel upset or distressed, contact a member of the research team for help.

12. Who is organising and funding the Map-HD Registry?

The registry is funded by the Australian Government's National Health and Medical Research Council (NHMRC). The funds come from a grant to Professor Julie Stout at Monash University. Professor Stout's research team led the development of the registry. The team worked with a committee called the Map-HD Working Group of the HDNA. The working group included clinicians, staff from HD State Associations, and people affected by HD.

We plan to support the registry using grant funding. The Australian Government, companies or charities may provide support for the registry.

13. Who has reviewed the ethics of the Map-HD Registry?

A Human Research Ethics Committee (HREC) reviews all registries in Australia. This committee is a group of people independent of the project. The HREC of Monash Health has approved the ethical aspects of the Map-HD Registry.

This registry complies with Australia's *National Statement on Ethical Conduct in Human Research (2018)*. This statement protects the interests of people who participate in human research studies and registries.

14. Further information and who to contact

For more information about the Map-HD Registry, contact Professor Julie Stout (Julie.Stout@monash.edu, 03 9905 3987) or Dr Yifat Glikmann-Johnston (Yifat.Glikmann-Johnston@monash.edu, 03 9902 0238).

Reviewing HREC approving this registry and HREC Executive Officer details

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| Reviewing HREC Name | Monash Health Human Research Ethics Committee |
| HREC Executive Officer | Executive Officer |
| Telephone | 03 9594 4611 |
| Email | research@monashhealth.org |

Consent Form

Non-Interventional Study – Parent / Legal Guardian consenting on behalf of child

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Consent Agreement for participation in the Map-HD Registry

I have read the Map-HD Registry Participant Information or someone has read it to me in a language that I understand. I have had any questions answered.

I consent to the personal information of the participant that I provide to the Map-HD Registry being used by Monash University for the purposes set out in the Participant Information.

I consent to the research team contacting me from time to time about updating the participant's profile.

I consent to participation in the Map-HD Registry as described. I understand that I am free to withdraw the participant at any time without it affecting their future health care.

The following statements are OPTIONAL. Tick the boxes of those you agree to. The participant can still participate in the Map-HD Registry if you do not tick the boxes.

- I consent to having my contact information shared with an HD State Association to enable them to contact me regarding the participant so they can provide information about support services and other opportunities related to HD.
- I consent to the participant's personal information (name, address, date of birth, sex and a data linkage ID) being disclosed to enable data collection from other organisations (such as Medicare, PBS, AIHW, NDIS, Enroll-HD site, etc.) to be linked to the participant's registry data.
- If the participant is an Enroll-HD participant, or becomes an Enroll-HD participant, I consent to the participant's data linkage ID being entered into the Enroll-HD database to enable a link between the Map-HD Registry and the Enroll-HD dataset.

Declaration by Parent / Legal Guardian - for Parent / Legal Guardian who has read the information

Name of child participant (type the participant's name here)

Name of person providing consent (type your name here to indicate your consent on behalf of the participant)

Relationship of person providing consent to the participant

I confirm that I am the parent / legal guardian of the child participant (tick box if true)

I confirm that I have the child's assent to participate (tick box if true)

Date _____

Only complete the section below if the person providing informed consent was unable to read these documents. In such a case, a witness must sign below. Otherwise, no witness is needed.

Declaration for Parent / Legal Guardian unable to read the information and consent form

Witness to the informed consent process

Name (type your name here to indicate you have witnessed the consent)

Date _____

*Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.