

## Participant Information

Non-Interventional Study - Adult providing own consent

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 <a href="mailto:Julie.Stout@Monash.edu">Julie.Stout@Monash.edu</a> phone (03)9905-3987
Associate Investigator	Dr Yifat Glikmann-Johnston email <a href="mailto:Yifat.Glikmann-Johnston@Monash.edu">Yifat.Glikmann-Johnston@Monash.edu</a> phone (03)9903-0238
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 to help you decide if you want to take part. 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 your care and services if you take part. Participation is free of cost.

To take part in the registry, you will need to consent. You consent by ticking boxes on the consent form and entering your name and date. The consent form follows this information.

You can download a copy of this information from the Huntington's Disease Network of Australia (HDNA) website at [hdna.com.au](http://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 if I join the Map-HD Registry?

To participate in the Map-HD Registry, you first need to provide consent. You then answer questions about yourself in the Map-HD Registry portal.

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

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

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

- Your CAG-expansion (or repeat number) if you have had the HD genetic test
- Which HD specialist clinicians or services you use, if any
- How far you travel to clinical appointments
- If you have accessed the National Disability Insurance Scheme (NDIS) or Aged Care services

#### Additional options: If you agree

- We will provide your contact details to an HD State Association.
- We will use your first and last name, address, date of birth, sex and a data linkage ID for linking to other datasets.
- We will contact you from time to time to request that you provide additional information to the registry and updates.
- 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 yourself and a person you care for.

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 REQUIRED Consent Agreement. Tick the boxes if you agree to the statements.

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 Participant', 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. 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. The summary page allows you to change your response to the optional consent items if you change your mind.

## **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 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, your 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 your contact details with a selected HD State Association

You can choose to share your 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. 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 Enroll-HD as well. 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 your data being linked to Enroll-HD, we will contact your Enroll-HD site. The details we will share with your Enroll-HD site are:

- 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 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 at [info@hdna.com.au](mailto:info@hdna.com.au).

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

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

If you withdraw, we will not collect additional information from you. We save the information you provided so far. Reports include your saved information as de-identified data. Tell the researchers if you do not want your 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 first. 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 your information collected and stored by the research team. 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  
Deborah Dell  
Phone: 03 9594 4605  
Email: [deborah.dell@monashhealth.org](mailto:deborah.dell@monashhealth.org)

If taking part causes you 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 is according to 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](mailto:Julie.Stout@monash.edu), 03 9905 3987) or Dr Yifat Glikmann-Johnston ([Yifat.Glikmann-Johnston@monash.edu](mailto:Yifat.Glikmann-Johnston@monash.edu), 03 9902 0238).

### Reviewing HREC approving this registry and HREC Executive Officer details

Name	Ms Deborah Dell
Position	Manager, Research Support Services and Human Research Ethics Committee
Telephone	03 9594 4605
Email	<a href="mailto:deborah.dell@monashhealth.org">deborah.dell@monashhealth.org</a>

## Consent Form

Non-Interventional Study - Adult providing own consent

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Location	Monash University
Registry Type	Self-Report Registry

### Consent Agreement for the REQUIRED Parts of the Map-HD Registry

You must accept all five statements below to participate in the Map-HD Registry. Tick the boxes if you agree. Do not tick the boxes if you do not wish to take part.

- 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 an opportunity to ask questions. If I did ask questions, I am satisfied with the answers I received.
- I freely agree to participate in the Map-HD Registry as described. I understand that I am free to withdraw at any time without it affecting my future health care.
- I consent to the personal information that I provide to the Map-HD Registry being used by Monash University for the purposes set out in the Participant Information.
- I understand that I can download a copy of the Participant Information to keep.

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

- I consent to the research team contacting me from time to time about updating my profile.
- I consent to having my contact information shared with an HD State Association to enable them to contact me about support services and other opportunities related to HD.
- I consent to my 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 my registry data.
- If I am an Enroll-HD participant or become an Enroll-HD participant, I consent to my 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 Participant - for participants who have read the information**

Name of participant (type your name here to indicate your consent)

\_\_\_\_\_

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 participants 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.