

Participant Information Sheet/Consent Form - Parent

Title	The Victorian Hip Dysplasia Registry
Short Title	VicHip
Protocol Version & Date	Version 2.0, dated 23/08/2023
Project Sponsor	Murdoch Children's Research Institute
Coordinating Principal Investigator	Associate Professor Leo Donnan

1 Introduction

Thank you for taking the time to read this Parent Guardian Information and Consent Form. We are inviting your child to take part in a research project because your child has Developmental Dysplasia of the Hip (DDH or Hip Dysplasia). The research project is aiming to develop improved early diagnosis and treatment pathways for children with Hip Dysplasia.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want your child to take part in the research. This form is 9 pages long. Please make sure you have all the pages.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether your child can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for your child to take part, they do not have to. They will receive the best possible care whether they take part or not.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to your child taking part in the research project
- Consent to your child having the tests and research that are described
- Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.



2 What is the purpose of this research?

VicHip (<https://vichip.org.au>) is an all-of-state registry. A registry is a collection of medical data on patients with similar conditions in Victoria, in this case Hip Dysplasia. Clinicians and researchers from Murdoch Children's Research Institute (MCRI), The Royal Children's Hospital (RCH), Monash Health, Western Health and Barwon Health will enrol participants state-wide, including smaller public and private practices.

Hip Dysplasia is very common in otherwise healthy infants. The hip is a "ball-and-socket" joint, where the femoral head (the "ball") sits in the acetabulum (the "socket"). The infant hip joint is made mostly of soft, flexible cartilage, rather than hard bone as in the adult. This means the hip joint(s) can more easily become unstable and may be misaligned or dislocate (come out of joint) completely. When left untreated, hip dysplasia may lead to early hip joint arthritis. Complete dislocations may lead to life-long disability.

Even though it is very common, there is no agreed standard for screening, diagnosis, and treatment of hip dysplasia. Clinicians use their experience and that of others to determine the best treatment. However, there is great room for improvement. Following many patients over a long period of time will show us how best to manage hip dysplasia.

By collecting your child's clinical information, radiology results and matching this with treatments and outcomes we can, with enough patients, start to understand the best treatment for each patient. For you and your child nothing different happens in your current treatment. Findings will be recorded at each visit with the results stored in a secure database along with thousands of children from Victoria. You and your child can't be identified in the database.

We will be working together with other researchers and clinicians with the same goals around the world. We will share VicHip data with the Global Hip Dysplasia Registry (GHDR; <https://hipregistry.com>) which aims to improve the lives of children with hip dysplasia internationally. Then we can work together to improve the outcomes of all children with Hip Dysplasia in Victoria, Australia and world-wide.

VicHip is working with GenV (short for Generation Victoria; <https://genv.org.au>). GenV is a research program run from the Murdoch Children's Research Institute. It is open to all Victorian children born over two years starting in October 2021, and their parents.

GenV and VicHip are inviting families of children with hip dysplasia to be in both studies. Our goal is to find better ways to detect and treat hip dysplasia, which could help people live healthier and more active lives.

3 What do we need to do in this project?

The study coordinator may ask you and your child to participate in VicHip at a clinic visit or while an inpatient at your hospital. They will give you information about the project and ask for your consent to take part. If you agree, the research team will record details about your child's condition into the registry. We hope to follow your child on their treatment journey, into adulthood, or when they are discharged from care. Your child can consent to the study once they are old enough, usually around 14-18 years of age.

Your child's treatment is the same whether or not you join VicHip. Your child has normal clinic visits and imaging whether they are in the registry or not.

Participation

After each clinic visit, your health professional and the research team will record information from your child's medical records into the registry database. This information includes general information, clinical assessment, ultrasound, x-ray, non-surgical and surgical treatment. We want to learn more about the costs associated with your child's hip dysplasia treatment. The research team will collect data from your child's hospital medical and costing records, such as the duration of hospital stays and what services were used for the planning of their care.

We will ask you and your child to complete short study surveys at various timepoints - at diagnosis, at 6 months, then every 1 to 4 years up until your child is 16 years of age depending on their treatment pathway. These surveys will ask about your experience, your understanding of health and healthcare and any costs involved, your child's function, pain, treatments and feelings. We will send you an email or text message when it is time to complete a survey. Even if your child is discharged from routine care, we hope you will still complete the later surveys.

Surveys will take between 5 and 20 minutes, depending on your child's age, treatment and outcomes. You don't have to attend the hospital to complete a survey - it can be done online. However, if your child has a clinic appointment around that time, you can do the survey at the visit. Once your child is old enough, we will also offer them short surveys, as well as the ones you fill out.

Communication

You may contact the principal investigators or study team regarding your child's participation at any time. We will communicate with you every 6-12 months about the project results in a newsletter and send survey reminders via email and SMS.

REDCap: Registry data is stored in REDCap database, stored by MCRI. REDCap is a secure web application that supports data capture for research studies. REDCap can also store contact details like your email address and telephone number. We use REDCap to send survey reminder emails or text messages.

You can read more about these forms of communications in the "Parents" tab of our study website; <http://vichip.org.au>.

4 Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

Your decisions - whether your child takes part, whether you withdraw later - will not affect their routine treatment, relationship with those treating them or relationship with your child's treating centre.

5 What are the alternatives to participation?

When consenting to VicHip you may opt out of completing VicHip surveys, allowing us to continue to collect your child's treatment data. You can also provide additional consent to share your contact information with GenV and share data between VicHip and GenV.

6 What are the possible benefits of taking part?

We are conducting this study for research purposes, with aims to progress our knowledge of hip dysplasia, therefore we cannot guarantee or promise that your child will receive any benefits from this research. However, we hope your participation will help us to improve care for future children with Hip Dysplasia.

7 What are the possible risks and disadvantages of taking part?

Whenever identifiable data is collected, there exists the risk of a potential loss of confidentiality. Please see Section 9).

There is a small chance that you or your child might become upset because you are taking part in this project. If this happens, you and your child can take a break from the surveys. We can arrange free counselling or other suitable support. This will be provided by someone who is not part of the research team. You may also decide to withdraw from the project.

We have tried to make sure that the questions in the surveys are sensitive and appropriate. However, if you or your child are worried by any of the questions, you do not need to answer them.

Participation in the registry does not change a patient's treatment. Decisions about treatment and surgery, are still made by the Parent with the support of their surgeon. No additional x-rays or clinic visits, other than that typically required of treatment, are added to your child's care.

8 What if my child is withdrawn from this research project?

If you decide to withdraw your child from this research project, please notify a member of the research team before withdrawal, you can do this via phone or email. A member of the research team will ask you to sign a study withdrawal form, this may be provided to you via email or post. You do not need to provide a reason for withdrawal or sign the withdrawal form if you do not wish to do so.

If you do withdraw consent during the research project, VicHip will not collect additional personal information from you or your child, although personal information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected by researchers up to the time your child withdraws will form part of the research project results. If you do not want them to do this, you must tell them before your child joins the research project.

9 What will happen to information about my child?

The MCRI is the data controller for this study. This means that they, as well as study investigators at your child's treating hospital, are responsible for looking after this information and using it properly. Any information obtained in connection with this research project that can identify your child will remain confidential except as required or permitted by law.

Your child will be given a unique study identification number which will be used for all the information we collect about them. Identifiable data is information with personal identifiers attached to it, including name, date of birth, UR number and email address. De-identified data is where we remove all personal identifiers from your information, including name, date of birth and email address and replace your child's name with a code.

Your child's identifiable and de-identified data will be entered directly into the REDCap study database, including a copy of the signed consent form/s. Data will be entered into this database by your health professional, study investigators and yourself, including the surveys. The identifiable and de-identified data will be stored separately within the database with restrictions on visibility and access. Only the study investigators will be able to re-identify your child.

Your child's information will only be used for the purpose of this research project and future research about DDH and it will only be disclosed with your permission.

Storage of information

Your child's de-identified research data, your/your child's contact details and consent forms containing personal information, will be stored securely in electronic format within the REDCap Study Database at the MCRI. The study is planned to be ongoing, and hence data will be stored for the duration of the study.

Unless you tell us to remove it, we will keep your and your child's data indefinitely. This means VicHip can support Hip Dysplasia for many years.

Information about participation in this research project may be recorded in your child's health records.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission. We will only publish or present group data to protect your child's privacy. You can read more about the storage of information in the "Parents" tab of our study website; <http://vichip.org.au>.

Right to access information

You have the right to access and correct the personal information we store about you and your child under privacy laws. You can do this by contacting VicHip.

Sharing information

To advance science, medicine and public health, we will share your child's **de-identified** data with the **GHDR** and may share your child's de-identified data with any current and future funders, research projects, biobanks, medical journals or data research repositories. Some of these organisations may be located overseas. **Any data that we send overseas is not protected by Australian laws and regulations.** By signing this consent form you are giving us permission to do this.

10 Who is organising and funding the research?

VicHip is led from the Melbourne Children's Campus (Murdoch Children's Research Institute, The Royal Children's Hospital, and the University of Melbourne). It is funded by The Medical Research Future Fund (MRFF). Associate Professor Leo Donnan is the Coordinating Principal Investigator (PI) of this project and an orthopaedic surgeon, you can read more about him and the VicHip team in the "Our Team" tab of our study website; <http://vichip.org.au>.

No member of the research team will receive a personal financial benefit from your child's involvement in this research project (other than their ordinary wages).

11 Further information and who to contact

The VicHip website <http://vichip.org.au> has answers to many questions, to contact a member of VicHip, please email us at vichip@mcri.edu.au. 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 the Director of Research Development & Ethics at The Melbourne's Royal Children's Hospital on (03) 9345 5044 or rch.ethics@rch.org.au.

For matters relating to research at the site at which your child is taking part, the details of the local site contact person are:

Contact person

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

Consent Form – Parent

Title The **Victorian Hip** Dysplasia Registry
Short Title VicHip
Protocol Version & Date Version 2.0, dated 23/08/2023
Project Sponsor Murdoch Children’s Research Institute
Coordinating Principal Investigator Associate Professor Leo Donnan

Declaration by Parent

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.

This project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee and is supported by my hospital. I understand that the project and any updates will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).

I understand that I will be given a signed copy of this document to keep.

I give permission for my child’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to my child’s treating centre concerning my child’s condition and treatment for the purposes of this project. I give permission for the collection of my child’s data from hospital medical and costing records for the purposes of this project. I understand that such information will remain confidential.

Name of Child (please print) _____

Name of Parent (please print) _____

Signature of Parent _____

Date _____

Declaration by VicHip Team Member

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent of the participant has understood that explanation.

Research Team Member

Name (please print) _____

Signature _____

Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Parent/Guardian Information Statement and Optional Consents – GenV/VicHip Collaboration

HREC project number: 87251
Research project title: The **Victorian Hip** Dysplasia Registry
Version number: 2.0 **Version date:** 8th September 2023

Generation Victoria (GenV)

Based on your child's date of birth, your family may be eligible to join GenV. VicHip is working with GenV.

What is GenV?

GenV, short for Generation Victoria (<https://genv.org.au>), is a research program run from the Murdoch Children's Research Institute (MCRI). It is open to all Victorian children born over two years from late 2021, and their parents. Many children are in both VicHip and GenV.

More about GenV

GenV is the largest childhood research project ever in Australia. It is painting a picture of how children grow and develop, how people age, and how health changes across generations. It creates the building blocks to help researchers, communities and policy makers to improve health and wellbeing together. We hope it leads to better and safer care, and answer some of the most important questions facing our children and parents. After two years, we will have invited over 160,000 babies and their parents across Victoria into GenV.

If you agree, we collect some information and samples from you and your child when you sign up to GenV, and then as your child grows up. Then, with your permission, we add information and samples that services already collect in normal practice. We put this information in secure data systems to be used in future research. Results will improve how we treat, predict, and prevent problems. They will also help policy makers make good decisions to support Victorian families.

This means that GenV takes little effort from you but creates meaningful change for families. We hope to study family health and wellbeing over many years.

Very big projects like GenV are already helping older adults around the world. We hope GenV will create these benefits for children and younger Victorians.

What does this mean for you and your child?

If you and your child are enrolled in GenV, VicHip and GenV would like to share information about you and your child. Then researchers can answer more questions on hip dysplasia, without more burden for you. GenV and VicHip store data in secure environments. Only authorised personnel can access the data to maintain your and your child's privacy and confidentiality. You can withdraw your consent for data sharing at any time – just contact VicHip at vichip@mcri.edu.au

Does my child have to take part in both studies?

No. Being in both VicHip and GenV is your choice. It's fine for your child to be in VicHip and not in GenV. However, being in both studies makes them more valuable.

Declaration by parent:

Please check one box on each line.

- I have read the VicHip/GenV Information Statement as well as the main VicHip consent form
- I will be given a copy of this document to keep
- I give permission for VicHip to share my contact details (including child's full name, date of birth, VicHip participant ID, my full name, email and mobile phone number) with GenV so that:

GenV can record we have joined VicHip:	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree
GenV may contact me so I can decide whether to join GenV (if my child is not already enrolled) ¹	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree
I give permission for VicHip and GenV to share my and my child's data for use in ethically-approved research (if my child is enrolled in both studies now or in the future)		
	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree

Name of Child (please print) _____	
Name of Parent (please print) _____	
Signature of Parent _____	Date _____

¹ If you are already in GenV please select "I agree". GenV will not contact you if you have already joined GenV.