

Participant Information Sheet/Consent Form - Parent

Title	The Victorian Hip Dysplasia Registry
Short Title	VicHip
Protocol Version & Date	Version 1.0, dated 18/07/2022
Project Sponsor	Murdoch Children's Research Institute
Coordinating Principal Investigator	Associate Professor Leo Donnan
Principal Investigators	AP Leo Donnan, The Royal Children's Hospital Dr Chris Harris, Western Health Dr Brian Loh, Monash Health Dr Richard Angliss, Barwon Health
Location	The Royal Children's Hospital, Barwon Health, Western Health, Monash Health

1 Introduction

This is an invitation for your child in your care to take part in this research project, VicHip because your child has Developmental Dysplasia of the Hip (DDH or Hip Dysplasia) or is being screened for the condition. 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. We just record the findings at each visit and put the results 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. Families in VicHip can also join GenV. VicHip supports this, as it contains extra data relevant to Hip Dysplasia and also lets us compare children with and without Hip Dysplasia. By being a part of GenV, you will help researchers find faster and better ways to predict, prevent and treat problems like Hip Dysplasia and other childhood conditions.

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, the research team will record information in 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 will ask you and your child to complete short study surveys at various timepoints - at diagnosis, at 6 months, 1, 2, 4 and 10 years of age, after treatments, after surgery, at skeletal maturity and at adulthood (18 years of age). These surveys will ask about your experience and any costs involved and 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.

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.

Electronic communications: To enable you to receive text messages, we will transfer some limited personal information (your name and mobile phone number) to a vendor. We have chosen platforms that will be stored securely and processed in line with applicable data protection and privacy laws and regulations. You can read more about these forms of communications in the "Parents" tab of our study website; <http://vichip.org.au>.

If your child was born in the GenV birth window (October 2021–September 2023):

For babies who are enrolled in VicHip but are not enrolled in GenV

With your consent, VicHip will confidentially share a small amount of information about you and your child with GenV. This may include your child's full name, date of birth, hospital UR number (the unique number assigned to patients or participant in research undertaken at a hospital, VicHip participant ID, and also your full name, email, and mobile phone number. This is so GenV can contact you and ask you if you want to be involved in GenV. You can ask questions and decide then.

For babies who are enrolled in both VicHip and GenV

With your consent, VicHip will confidentially share a small amount of information about you and your child with GenV. This means both VicHip and GenV know that your child is in both studies. This may include your child's full name, date of birth, hospital UR number, VicHip participant ID and your full name, address, and mobile phone number.

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 the institution or 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 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 and to comply with law. 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 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.

Optional consent

Data sharing for babies who are enrolled in VicHip and GenV

If your child is enrolled in GenV or enrolls in GenV later, we also ask your permission for the two studies to confidentially share data. GenV is a state-wide research project that is collecting and combining data from a wide range of services to draw a picture of children's health and wellbeing in Victoria. Information collected in the VicHip registry will be transferred to the secure GenV data environment and connected to your child's existing data. Information collected by GenV will also be transferred to the VicHip Registry. This makes both studies more valuable. For example, they can answer more questions about Hip Dysplasia (including family history, previously unknown risk factors and long-term outcomes) without more time from you. Data will be stored in secure environments of the two studies. Only authorised study staff and researchers 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 the VicHip Coordinator on 0413 589 213 or at melissa.formosa@mcri.edu.au. If you withdraw your consent no further data will be shared between the studies. Any data shared before withdrawal will not be removed from the VicHip or GenV databases.

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 or vice-versa.

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 has answers to many questions, to contact a member of VicHip, please call Melissa Formosa the Clinical Research Coordinator on 0413 589 213 or email melissa.formosa@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.