



HREC Project Number: HREC/17/RCHM/334
RCH HREC 37278A

Research Project Title: ANZ CLARITY – Establishment of a National Juvenile Idiopathic Arthritis Biobank.

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Version Number: V6 **Version Date:** 24/02/2020

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite you and your child to participate in a research project that is explained below.

This document is 11 pages long. Please make sure you have all the pages.

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Important things you need to know

- It is your choice whether or not your child can take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child gets at The Royal Children's Hospital.

If you would like your child to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project

We will give you a copy of this information and consent form to keep.

1. What is the research project about?

In this research project, we are establishing a national Juvenile Idiopathic Arthritis biobank, called ANZ CLARITY (Australia and New Zealand Childhood Arthritis Risk factor Identification sTudY).

Juvenile Idiopathic Arthritis, or JIA for short, belongs to a group of illnesses called autoimmune diseases. Your body has an immune system, which fights germs and keeps you healthy. In autoimmune diseases the body's immune system mistakes a normal part of the body for something foreign (like a germ), and starts attacking the body itself. In JIA the immune system attacks the joints and sometimes other body tissues. This is called an autoimmune process and we do not understand exactly how and why this happens. The symptoms of JIA are joint pain and swelling, stiffness (especially in the mornings), difficulty moving and sometimes fevers and rash.

The ANZ CLARITY Biobank will collect people's body fluid samples, such as, blood, saliva and synovial fluid. These samples are called biospecimens. It will also collect people's personal and health information. This is often referred to as data. The biospecimens and personal and health information will be stored at the Murdoch Children's Research Institute (MCRI). They will be used for research.

In 2008 the researchers started a Victorian JIA biobank called CLARITY (Childhood Arthritis Risk factor Identification sTudY) so they could look at children's genes and environment to see how they might make some children more likely to develop JIA. In an effort to increase the number of children participating in the biobank we are now extending our biobank to include children and their families with and without JIA from across Australia.

By establishing a national JIA biobank we will have a greater chance of discovering why some children are more likely to develop JIA. We may also learn why some children with JIA develop a worse type of the illness than others. Long term, we hope that the new information will help researchers develop new treatments, come up with ideas for prevention, and better care for children and young people living with JIA.

2. Who is funding this research project?

The National Health and Medical Research Council (NHMRC), Murdoch Children's Research Institute (MCRI), and other philanthropic organisations have provided funding for this research.

3. Why is my child being asked to take part?

We are asking your child to take part because your child is under the age of 18 years and has been diagnosed with JIA.

4. What do my child and I need to do in this research project?

If you and your child take part in this research we will need you and your child's rheumatology doctor to fill out a questionnaire, and your child to give us a blood sample.

I. Questionnaire

We would like you and your child to complete a questionnaire. The questionnaire will ask questions about your child's home environment, health, and you and your child's family history. This information is really important when looking at how genes and the environment might act together to cause JIA.

It's a good idea to have your child's My Health & Development Record with you to help fill in the questionnaire. This is the booklet you were given at the hospital when your child was born.

We will provide you with an iPad or computer at one of your child's rheumatology clinic appointments to complete the questionnaire. It will take about 20 minutes to do.

If you can't answer all the questions because you need to check with your child's records at home or with a family member, we can follow-up the missing information over the telephone at a pre-arranged time that is right for you.

If completing the questionnaire in clinic is not possible, we can email you a link to the questionnaire so you can fill it out at home. We can also give you a paper copy of the questionnaire if you prefer.

II. Blood sample

With your consent we would like to collect a blood sample from your child for processing and storage in the ANZ CLARITY Biobank.

Where possible, we will do this at the same time your child is having one of their regular blood tests to look after their JIA. That way no extra needles or appointments are required. The study coordinator will coordinate with the blood collecting service at the time of your child's routine blood test. They will collect an extra 10-20mls (2-4 teaspoons) of blood from your child.

With your child's blood sample, we can learn how your child's immune system is working. We will look to see if there have been any changes in your child's DNA that might be relevant to developing immune diseases like JIA. DNA is an essential molecule for life. Think of it like a recipe holding the instructions telling our bodies how to grow and work.

If collecting a blood sample at the same time as a routine blood test is not possible, with your consent, your child can still provide a blood sample for the biobank. When it is convenient for you and your child a nurse trained in collecting blood from children will collect your child's blood sample.

Before your child's blood test, the blood collection service, or our study nurse will offer to put a patch of numbing cream to the area of skin on your child's arm where the blood sample will be collected.

If you or your child do not want to or cannot give a blood sample today, that's ok. Your child can still participate by providing a saliva sample. However, if possible it is better we obtain a blood sample. This is because a blood sample will help us get much more information about the details of your child's illness. Your child can provide a blood sample any time in the future, when the time is right for you and your child.

III. Synovial Fluid sample

A joint injection is a common way to treat JIA. Joint injections reduce inflammation and pain in swollen joints. Your child's rheumatology doctor inserts a needle into the space between the bones in a joint. The doctor then removes some of the excess joint fluid, called synovial fluid, from the inflamed joint before injecting a long-acting steroid medicine into the joint.

If your child has a joint injection at any time as part of the management of their JIA, we would like your consent to collect the synovial fluid for processing and storage in the ANZ CLARITY Biobank alongside other samples and information you/your child has given us. This synovial fluid would otherwise usually be discarded. Your child does not need to do anything extra to provide this sample to the research project.

If your child does not have a joint injection, we will not collect a synovial fluid sample from them.

IV. Clinicians Questionnaire

With your permission your child's rheumatology doctor and/or team will also fill out a questionnaire about your child's JIA and health using your child's medical record.

Your child's doctor/team will provide us with information such as the following:

- when your child's JIA symptoms began
- when you child was first sent to see a rheumatology doctor and who referred your child
- the date your child was first seen by a rheumatology doctor
- your child's most recent height and weight measurements
- any medications your child has taken and are now taking
- if your child has had any other illnesses/diseases
- your child's family history
- any recent blood test results
- your child's JIA disease activity
- what type of JIA (sometime called JIA sub-type) you child has been diagnosed with

The ANZ CLARITY Biobank team and/or your child's rheumatology team may need to go back to your child's medical record from time to time to gather further information, such as:

- confirm your child's diagnosis of JIA , including what type of JIA your child has
- look at how your child's JIA has got better or got worse

5. Optional consent

We are asking for your consent to collect, process, and store your child's blood/saliva and data for JIA research. We would also like you to consider providing extended consent for your child's samples and data to be used for other future research projects. These options are:

OPTION 1: Extended consent for future use of biospecimen and data for other immune or musculoskeletal disorder research:

We would like you to consider letting us store your child's body fluid samples and data collected as part of this study, for use in future ethically approved research studies related to other immune and musculoskeletal disorder research. For example, we might want to examine how JIA is similar or different to other childhood immune disorders like type 1 diabetes, or food allergy, or we might want to understand more about how the musculoskeletal system works in children generally.

If you give your permission, we will store your child's body fluid samples and data at the MCRI for an indefinite period of time. The samples and data will be stored using a special ID number. Your child's name will not be attached to the samples or data. We do not plan to contact you and your child if the samples or data are used in future research. Any future research for which your child's samples or data are used must first be approved by an ethics committee and by the ANZ CLARITY committee looking after your child's samples and data.

Please tick the appropriate box on the consent form to let us know if you consent to this or not.

OPTION 2: Access to Newborn Screening Card – VICTORIAN BORN CHILDREN ONLY:

If your child was born in Victoria we would also like your permission to access your child's Newborn Screening Card (NBS or also known as a Guthrie card) stored at Genetic Health Services Victoria (GHSV). All newborn Victorian babies have a heel prick blood test taken in the first few days of life by a midwife. The blood is tested for serious and treatable diseases. The remaining spots of blood are stored as a NBS card at GHSV under the provisions of Health Information Privacy Legislation of Commonwealth and State governments.

Each newborn screening card usually has 4 dried spots of blood that are 12mm across. With your consent we will remove 1 blood spot to look at your child's birth blood components to see if they are different to the birth blood components of children without JIA. The sample is important. It is a pre-disease blood sample, which may contain important information about your child before they were diagnosed with JIA. At least one of your intact blood spots will be kept by GHSV. This means if we ask GHSV for your blood spot and there is only one left we will not access your blood spot for this part of the research.

We are asking permission to access your child's individual NBS sample. That way the ANZ CLARITY Biobank can link your child's pre-JIA blood spot from your child's NBS card with your child's post-JIA blood sample and data collected for this study. Together the information can become part of the ANZ CLARITY Biobank for use in research.

You can choose to allow us to access your child's NBS card for use in:

- a) this project only, or
- b) in this project **and** further ethically approved projects related to immune and musculoskeletal disorders. This is called ongoing use. If you consent to ongoing use of your child's NBS card, we will not contact you again to ask for your permission to use your child's sample. GHSV will always keep at least one of your child's intact blood spots.

If you consent you will be asked to provide the following personal information so we can use this information to confirm we have correctly identified your child's NBS card: Your child's name and date of birth (DOB), Mother's name (at time of your child's birth) and DOB and hospital where your child was born.

OPTION 3: Contact for Additional Information for Future Research:

Establishing a national JIA biobank is a positive step towards answering many current questions about JIA. As researchers it is impossible for us to predict all future research questions we might have about JIA and other childhood conditions. We don't know what other information or samples we may need to collect to help answer future questions. Therefore we are asking you and/or your child whether you/they would be willing to be contacted by us in the future about opportunities to participate in further research where new information or samples need to be collected.

If your child is 18 years or older at the time of future contact we will be asking your child to consider and provide their consent for participation in any future research.

You and your child will only be contacted about a research project your child qualifies for. If such a project comes up and you have given us permission to contact you and your child we will identify your child using the information provided to us when your child first enrolled in the Biobank.

The long-term goal of the ANZ CLARITY Biobank is to build a biobank over many years. The larger the biobank grows, the greater the power it will hold to understand causes of JIA, and to improve the prevention, diagnosis and treatment of JIA. By consenting to be contacted in future and providing, if needed, more samples and/or information about your child and their JIA, we can continue to work towards answering questions we have now and in the future.

If you agree to you and your child being contacted for future research projects where new information or samples are required, you can do this by checking the box on the consent form.

You and your child do not have to take part in any future research that you are sent information about.

6. What will my information be used for?

In this project, we will collect and use information from your child's medical record for research purposes. Your child's rheumatology doctor or/and team will need access to your child's medical record to fill in clinician questionnaires, record medical information about your child's health, JIA and treatments. For example, medications and/or procedures your child has had. This information along with the personal and health information you give us when you complete the child and parent questionnaire will be stored in the biobank's secure database.

We may also need to go back to your child's medical record if you've provided consent for future research related to the use of your child's samples stored in the ANZ CLARITY Biobank.

7. Can my child withdraw from the project?

If you give your consent and later change your mind, that's ok. You can stop your and your child's involvement in the biobank at any time. You do not need to tell us why you want to stop your child being in the project. If your child leaves the project we will use any information already collected unless you tell us not to. At the time of withdrawal we will ask you to select one of the options below, so that we are clear about what you would like us to do with your samples and data:

OPTION 1 - No further contact with you or your child, but gives us, the researchers, permission to retain and use your child's samples and data, and to access further information from your child's medical records.

OPTION 2 - No further access or contact with you or your child or their medical records but gives permission to keep and use your child's samples and data you have given us.

OPTION 3- No further use of any health information, data or samples previously collected as well as no further contact with you or your child or access to your child's medical records. The ANZ CLARITY Biobank will destroy your child's samples and will hold information relating to your child only for archival and auditing purposes. A copy of your child's participant information and consent form and withdrawal will be kept as a record of their/your wishes. Information about your child will not be included in any future analyses however it will be impossible to remove your child's data from completed research.

It's important to know that if your child's samples or data have already been used for purposes of an approved research project, or if the results have been published at the time of withdrawal, it will not be possible to delete your child's data from the completed projects.

8. How do I keep my child informed?

At the time of your child's enrolment in the ANZ CLARITY Biobank you will be provided with an alert sticker. Please stick this inside your child's My Health & Development Record. This is a reminder that your child is enrolled in the ANZ CLARITY Biobank and has details of who to contact if you or your child want to find out more about your child's samples and personal and health information.

As parents/guardians providing consent for the collection, processing and long-term storage of your child's samples and data we strongly encourage that you continue to talk with your child about their participation and how they can contact the ANZ CLARITY Biobank team for more information about their participation.

Your child will not be re-contacted at 18 years of age to be re-consented.

9. What are the possible benefits for my child and other people in the future?

There are no direct benefits to you and your child.

Being part of this research may make you and your child feel part of the larger effort working towards a solution for JIA. This may help you; your child and your family feel more positive towards your child's arthritis care.

The findings could help us learn more about trying to prevent JIA among children and help find new treatments. Your contribution could also help us learn more about other childhood disorders.

10. What are the possible risks, side effects, discomforts and/or inconveniences?

We do not expect there to be any major risks, side effects or discomforts.

If your child is having a blood test, there is a possibility that your child may feel some discomfort during the procedure. Where possible, we will take a blood sample for this research project at the same time as other blood tests are happening. We can use a cream to numb the skin before the blood sample is taken. It is possible some bruising may occur at the needle site. To minimise any problems, the samples will be taken by a health professional trained in collecting blood from children.

This study is only searching for genes that are related to JIA. Genes are a set of instructions inside all of the cells that make up our body. However, other future studies may be searching for other information. Therefore there is a very small risk that we may find genes responsible for other conditions that you and your child do not know about. If we find that your child may have any condition that you do not know about, we will call you to talk about what we have found and, if needed, organise for you and your child to see a relevant health professional for care and support.

The possible inconvenience is the time it takes for you and your child to complete the questionnaire, and for the body fluid samples to be taken.

11. What will be done to make sure my child's information is confidential?

In this study we will collect and use body fluid samples and personal and health information about your child for research purposes. Any information we collect that can identify you or your child will be treated as confidential. It will be used only in this project, unless you tell us otherwise on the consent form at the end of this document. We can pass on the information only with your permission, except as required by law.

The Genes, Environment & Complex Disease Group at the MCRI will store all of your child's information securely.

The following people may access information collected as part of this research project:

- the ANZ CLARITY Biobank research team involved with this project
- the Royal Children's Hospital Human Research Ethics Committee
- local governance officers from participating national associate sites

The information will be re-identifiable. This means that we will remove your child's name and give the information and samples a special code number. Only authorised members within the biobank research team can match your child's name to their special code number, if we need to. Your child's samples will be kept in a freezer in a locked laboratory at MCRI.

All samples and data collected from you and your child and stored in the ANZ CLARITY Biobank will be kept indefinitely in secure storage for future JIA and other research, unless you tell us you don't want us to anymore. If the biobank were to close down or the research was to stop, we will try very hard to let you know via email, mail and the ANZ CLARITY website. Your child's samples and data will not be destroyed but will stay stored, be looked after and used in ethically approved research by the ANZ CLARITY Biobank's researchers at the MCRI.

If you have given your consent for us to keep your child's samples and data for use in another research project, we will keep it once this research project is finished. If you haven't given consent for us to use it again, we will destroy the samples.

When we write or talk about the results of this project, we will report information about the whole group of participants. This means that no one will be able to identify you or your child. Every effort will be made to protect you and your child's confidentiality and privacy when sharing samples and data with other researchers.

Your child's sample may be sent to another laboratory for testing because some specialised testing cannot be performed here at the MCRI. Any samples sent from the MCRI ANZ CLARITY Biobank to another laboratory will be labelled with your child's special code number only. It will not be possible for the testing laboratory to identify your child's sample.

In the future other researchers working in the areas of JIA and autoimmune diseases may request access your child's samples and data. These researchers will need to apply to the ANZ CLARITY Biobank committee for permission to use your child's samples and data. The biobank will only release your child's samples and data to other researchers once their application has been approved by the ANZ CLARITY Biobank committee and by an authorised ethics committee.

Australian laws and regulations will not protect any samples and data sent overseas. However, we will develop our own legal contracts to ensure that your child's sample or data are protected.

12. Will we be informed of the results when the research project is finished?

The overall results will be published in the medical journals. These results will be presented at a group level, where no one will be able to identify any individual participant. The **ANZ CLARITY website** (www.mcri.edu.au/clarity) will publish the results of studies. We will not report on individual results.

13. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the biobank team, please contact:

Name: A/Prof Jane Munro
Contact telephone: 03 9345 6437
Email: clarity.study@mcri.edu.au
Website www.mcri.edu.au/clarity

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

CONSENT FORM

HREC Project Number: HREC/17/RCHM/334
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- I have read, or someone has read to me in a language that I understand, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to the storage of my child's body fluid samples and data for use in future ethically approved research projects related to other child immune and musculoskeletal conditions.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not OR <input type="checkbox"/> Child not born in Victoria	Consent to the access and use of my child's already stored Newborn Screening Card sample for this research project. If yes, Please provide the following additional information required to gain access to your child's card: Mother's name at time of birth of child: Mother's Date of Birth: Child's Hospital of Birth:
<input type="checkbox"/> I do	<input type="checkbox"/> I do not OR <input type="checkbox"/> Child not born in Victoria	Consent to the ongoing use of my child's Newborn Screening Card for use in future ethically approved research projects related to other child immune and musculoskeletal conditions.
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to be contacted about future research projects where additional samples or data are required.



Child's Name

Child's Date Of Birth

Parent/Guardian Name

Parent/Guardian Signature

Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.