Parental Consent Form
for parent to complete for child under 18 years of age

Title of Research Study 00001169: Creating a Minnesota Statewide Population-based Study of Children with Juvenile Idiopathic Arthritis

Researcher Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

<table>
<thead>
<tr>
<th>Researcher Name: Colleen Correll, MD, MPH</th>
<th>Study Staff (if applicable): Michelle Roesler</th>
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</thead>
<tbody>
<tr>
<td>Phone Number: 612-625-6806</td>
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<td>Email Address: <a href="mailto:corr0250@umn.edu">corr0250@umn.edu</a></td>
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Supported By: This research is supported by the University of Minnesota Department of Pediatrics “R” award.

Doctors at the University of Minnesota, including Dr. Colleen Correll, are interested in both your child’s clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

What is research?
Doctors and researchers are committed to your child’s care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Medical research is research that focuses on identifying causes of disease, improving the quality of life and extending the life of those with illnesses. To do this, some researchers conduct studies that involve human subjects. Your child, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help your child get better or to improve quality of life. Doctors can make changes to your child’s treatment plan as needed.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a parent of a patient with juvenile idiopathic arthritis (JIA) who is less than 16 years old and you live in the state of Minnesota.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you and your child take part is up to you.
- You can choose not to take part.
- You can agree to have your child take part and later change your mind.
- Your decision will not be held against you or your child.
- You can ask all the questions you want before you decide.
Why is this research being done?
The purpose of this study is to create and maintain a registry, which is a database (a searchable collection of information) about children and adolescents with juvenile idiopathic arthritis (JIA). This data may help in the evaluation of triggers for JIA onset or disease flare. Researchers think this information will help improve future treatments and health outcomes. In addition, this registry will help to identify patients who may be eligible for future studies.

How long will the research last?
This is a registry. Participation in registry-based studies continues for as long as you and your child agree. When your child turns 18 we will ask him/her whether or not he/she would like to continue participation.

How many people will be studied?
We expect to include about 800 patients and their family members. We expect approximately 2,400 people will be in this research study through the University of Minnesota.

What happens if I say “Yes, I want to be in this research”?
If you agree to have your child in this study, you will be asked to sign this permission form and we will give you a signed copy to keep. We will ask you to complete a contact information sheet and sign a medical records release form.

Baseline Information

- We will collect information about your child which will come from you, your child’s physician, and medical record. This information includes:
  - Your and your child’s current contact information
  - Demographic information (date of birth, age, race, ethnicity, sex)
  - Results from your child’s physical exam (height, weight, pulse rate, joint exam, etc.)
  - Medical information (the medications your child is taking, your child’s medical history, other medical conditions your child has and family medical history)
  - Your answers to questions about how your child’s disease is affecting his/her life and how your child feels. These questions will take about 15 minutes to complete.
  - Your answers to questions about the physical environment.
  - Your child’s Social Security number (if you are willing to provide it)
  - Health insurance information and health insurance identification numbers (if you are willing to provide this)

- We will collect information from your child’s birth certificate and if available a portion of the newborn screening blood spot screening card through the Minnesota Department of health (MDH) and other states for those born outside of Minnesota. This information includes:
  - Maternal health during pregnancy
o Birth history (for example, whether your child was born full term or preterm and type of delivery)
o Baby’s health soon after birth (for example, baby’s weight and if there were any complications after birth)
o If available, we will collect a portion of the newborn screening blood spot taken approximately twenty four hours after your child’s birth.

• We will collect a saliva sample from you, your child, and your child’s other parent (or sibling) to look at DNA.
  o Saliva Sample for DNA collection:
    ▪ We would ask you and your child’s other parent to donate a saliva sample. The saliva sample will be collected by having you spit into a sample container. Samples will be collected at the time of your child’s rheumatology clinic appointment or it can be returned to us using the pre-paid mailer. This part of the study takes about 10 minutes. If we find out that your sample does not have enough DNA to be useful, we may call you for a replacement sample.

Follow-up Information

• How often will the follow-up visits take place?
  o After enrollment, your child will continue to see his/her doctor based on your child’s normal clinic visits. Follow-up information will be collected at least every 6 months.

• What information will be collected about my child?
  o Review of contact information
  o The medications your child is taking
  o Results from your child’s physical exam (height, weight, pulse rate, joint exam, etc.) and labs, tests and other information from your child’s medical record.
  o Medical information about how the disease is affecting your child
  o Answers to questions about how the disease is affecting your child’s life and how your child feels. These questions will take about 15 minutes to complete.
  o Answers to questions about your physical environment.
  o Updated health insurance information and review of your child’s health insurance identification numbers (if you are willing to provide this)

• How will the follow-up information be collected?
  o Follow-up information will be collected from you, your child’s physician, and your child’s medical record. This information may be obtained in the following ways:
    ▪ During your child’s routine doctor visit
    ▪ Over the phone
    ▪ Web-based surveys
    ▪ Mobile application that runs on smart devices (smartphone, tablet, etc.)
Genetic Information

We are collecting DNA from saliva samples. Our laboratory is a research laboratory. This means that our studies are being performed to learn about genes that may be associated with juvenile arthritis. Because this is a research study, we will not give you results of the genetic testing. Participation in this research study does not replace any genetic tests that your child’s healthcare provider may have recommended.

While we are not planning to give out any results of genetic testing, there may be rare situations where we find genetic changes that could significantly impact your child’s medical care. If our laboratory should identify a genetic variant that impacts medical care, called “medically actionable findings,” we will ask your child’s physician to have the result verified in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. We will provide information to the laboratory to allow them to complete the testing. This additional testing in a clinical CLIA laboratory will usually require a new sample and be charged to insurance as a clinical laboratory test. At the end of this consent form, you may choose whether or not you want to be contacted with any “medically actionable findings.”

What happens if I do not want to be in this research?
Your child does not have to participate in this study. Your child can get treatment or care for his/her illness even if he/she is not in this research study.

What happens if I say “Yes”, but I change my mind later?
You can have your child leave the research at any time. Leaving will not be held against you or your child.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your child’s right to any present or future medical treatment.

If you decide to have your child leave the research, contact the investigator so that the investigator can discard your child’s samples. If you decide to withdraw from this study after your child’s DNA has been analyzed, the genetic information will be discarded and will not be used in this portion of the study. However, research already done on those samples cannot be undone.

What are the risks of being in this study? Is there any way being in this study could be bad for my child?
There are no physical risks to your child. Your child’s medical care will not change because he/she is taking part in the registry. You and your child’s doctor will keep making all the decisions about your child’s treatment and care. There is a potential risk of loss of confidentiality. We will, however, make every effort to protect confidential information to minimize this risk. You may refuse to answer any of the questions. Your child may stop his/her
participation in this registry at any time.

**Genetic information**
- The testing in some cases may reveal information not anticipated. For some DNA testing, this includes information about paternity or blood relationships between the people being tested. We will not tell you this type of information if we find it unless it affects your child’s medical care.
- Your child’s DNA sequence is like a fingerprint: it is unique to your child. All precautions will be taken to protect your child’s privacy and confidentiality. All genetic information will be stored in a secure database that is labeled only with an identification number. Only Dr. Correll and qualified researchers will have access to these data.
- If you decide that you want to receive “medically actionable findings,” it is possible that we will tell you that your child is at high risk for a serious medical condition. In most cases, we do not expect to identify medically actionable results.

**Will it cost me anything to participate in this research study?**
Taking part in this research study will not lead to any costs to you.

**Will being in this study help me in any way?**
There will be no direct benefit to your child or your family. We hope that the information learned from this study will benefit other people with your child’s condition in the future.

**What happens to the information collected for the research?**
Efforts will be made to limit the use and disclosure of your child’s personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your child’s information include the Institutional Review Board (IRB) and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Research that uses your child’s samples might be done a long time after the sample has been collected. The samples will be used for research by Dr. Colleen Correll and qualified researchers for the purposes of learning more about juvenile idiopathic arthritis and similar conditions. If you agree to let us use your child’s sample for this additional portion of the study, it will be labeled with a number, not your child’s name, and kept indefinitely. Your child’s identity would always remain private and would not be provided with the samples.

**Will anyone besides the study team be at my consent meeting?**
You may be asked by the study team for your permission for an auditor to observe your consent meeting (or a recording of your consent meeting). Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not record any personal (e.g. name, date of birth) or
confidential information about you or your child. The auditor will not observe your consent meeting (or a recording of your consent meeting) without your permission ahead of time.

**Who do I contact if I have question, concerns or feedback about my experience?**
This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants’ Advocate Line at 612-625-1650 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**Will I have a chance to provide feedback after the study is over?**
After the study, you might be asked to complete a survey about your child’s experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the “Who Can I Talk To?” section of this form for study team and HRPP contact information.

**What else do I need to know?**
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that your child has suffered a research related injury, let the study physicians know right away.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect your child in the following ways:

- Health insurance companies and group health plans may not request your child’s genetic information that we get from this research.
- Health insurance companies and group health plans may not use your child’s genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your child’s genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
Will I be compensated for my participation?
Your child will not be paid for participation in this registry.

Use of Identifiable Health Information
We are committed to respect your child’s privacy and to keep personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child’s personal health information that includes health information in medical records and information that can identify your child. For example, personal health information may include name, address, phone number or social security number. Those persons who get health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

The researcher may contact me in the future to see whether I am interested in having my child participate in other research studies by the Principal Investigator of this study.

The researcher may retain any leftover saliva sample taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my child’s identity.

In the rare event that potentially medically actionable results are found the researcher should inform me.
Your signature documents your permission for the above named child to take part in this research.

Signature of Parent or Guardian

Printed Name of Parent or Guardian

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s participation in the research. Contact legal counsel if any questions arise.

Assent:

[ ] Obtained verbally without a signature
[ ] Not obtained because the capability of the child is so limited that the participant cannot reasonably be consulted.

Signature of person obtaining consent and assent

Printed name of person obtaining consent and assent