

Parent/Guardian Consent Form
For parents/guardians of children between birth to 15 years old

Title of Research Project

CALIPER: Canadian Laboratory Initiative on Paediatric Reference Intervals

Investigators

Dr. Khosrow Adeli, Primary Investigator, 416.813.8682

Dr. David Colantonio, 416.813.6817

Dr. Lianna Kyriakopoulou, 416.813.8066

Coordinators

Jennifer Pinto, 416.813.7654 ext. 2673

Man Khun Chan, 416.813.5904

Assistants

Victoria Bevilacqua

Sarah Delaney

Purpose of the Research

CALIPER is a nation-wide initiative to create an updated database of 'paediatric reference intervals' - a range of blood test results obtained from a group of healthy children to determine what is normal when a child with medical concerns is screened for a disease. Your child's blood sample will help to fill in the critical gaps that currently exist with respect to age, gender, and ethnicity. This will help to improve assessment and treatment of children at SickKids and across Canada.

Description of the Research

Step 1: Questionnaire and Consent Form

You will complete a short questionnaire and sign a consent form, which will take about 10-15 minutes. To review this questionnaire and consent form, please go to www.caliperproject.ca. You can print and complete the questionnaire and consent form at home, or at your child's appointment, where a SickKids CALIPER team member will be available to assist you. Upon request, a hard copy can be mailed to you. If your child will be participating at a school clinic and if you will not be accompanying your child, please be sure to complete the questionnaire and sign the consent form before your child's appointment.

Step 2: Schedule Your Child's Appointment

If your child will be participating at a school clinic, your child's school will schedule your child's appointment. If your child will be participating at SickKids or at a nearby CALIPER site such as Gamma-Dynacare, please contact the Project Coordinator, Jennifer Pinto at 416.813.7654 ext. 2673 or jennifer.pinto@sickkids.ca to schedule an appointment for your child. It is not necessary for children to fast for this study. However, if you decide to fast, the fasting period will depend on your child's age (before next feeding for children less than 2 years old; 4-6 hours before next meal for children between 2-12 years old; and a minimum of 8 hours before breakfast for children 13-18 years old).

Step 3: Day of Your Child's Appointment

Upon arrival you will be greeted by a CALIPER team member who will review the details of the project with you and can also help you fill out the questionnaire and consent form. Depending on your child's age, you and/or the CALIPER team member will explain the blood donation procedure to your child. You and the CALIPER team member will then sign this consent form. The CALIPER team member will ask you/your child a few questions (e.g. your child's recent diet and exercise) and take a few measurements (e.g. your child's height, waist and weight). If your child is between 8-15 years old, he/she will be asked to complete a Tanner form, which is a measure of pubertal development. A phlebotomist experienced with paediatric blood collection will then take a one-time small blood sample from your child's arm, which will take about 5 minutes. No other visits or additional tests will be needed.

Step 4: Follow-up with Your Child's Doctor

We will share your child's blood test results that could be of concern with your child's doctor (and also normal blood test results if you wish). Your child's doctor can then share these results with you. With your permission and if your child is between 9-15 years old, we will ask your child's doctor to share your child's Tanner results with us (that is if your child did not complete her/his Tanner form at the appointment).

Participation

Participation in this study is voluntary. If you choose to let your child take part in this study you can take your child out of the study at any time. If your child should ever need care at SickKids, this will not be affected in any way by whether your child takes part in this study. New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study. If your child becomes ill or is harmed because of study participation, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, and any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Sponsorship

Funding for this project is provided by SickKids Department of Paediatric Laboratory Medicine (DPLM) as well as the Sanford Jackson Endowment.

Potential Benefits to Participants

In addition to knowing one has helped children and teens with medical concerns across Canada, participants themselves (and/or family member or friend) could potentially be a patient at SickKids or other paediatric health centre, and benefit directly from the results obtained from this study.

Potential Benefits to Society

The major benefit of this project will be an accurate and reliable determination of what is healthy and normal when a child with medical concerns is screened for a disease. This in turn will contribute to better assessment and treatment of children at SickKids and across Canada.

Potential Harms

We will collect a small blood sample from your child's arm using a needle (e.g. butterfly needle). There may be slight discomfort, bruising or redness that will usually disappear within a few days. For many participants, applying pressure with a cotton ball immediately after blood donation can help alleviate any bruising or redness. Blood donation is usually a quick process (about 5 minutes). Depending on the child's comfort level, it can sometimes take a little longer. While the amount of blood that will be collected is small, the impact that it will have in terms of helping children with medical concerns is immeasurable.

Potential Discomforts or Inconvenience

Your child's appointment will be scheduled at a time and location that is convenient for you (e.g. at SickKids or nearby CALIPER site such as Gamma-Dynacare). In special cases, we can come to your home to collect your child's blood sample. Total participation time, excluding travel to and from your child's appointment, will be approximately 15-20 minutes.

Confidentiality

We will respect your privacy. All data is strictly confidential and will be used only for this research project and our collaborative work with Dr. Patricia Parkin at SickKids. No information about who you are or who your child is will be given to anyone or be published without your permission, unless required by law. That is, we are required by law to report to the proper authorities if it is believed that a child has been abused, if someone has an illness that could spread to others, if someone talks about harming themselves or others, or if the court orders us to give them the study papers.

SickKids Clinical Research Monitors, employees of the funder (SickKids DPLM and Sanford Jackson Endowment), or the regulator of the study may see your questionnaire responses or your child's blood test results to check on the study. By signing this consent form, you agree to let these people look at this information.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the study the data will be kept as long as required then destroyed as required by SickKids policy. Published study results will not reveal your identity or your child's identity.

Reimbursement

Each participant will receive the following for donating blood:

- \$10
- blood test results
- two volunteer hours
- chance to win a laptop
- choice of t-shirt, teddy bear, or storybook

The above-mentioned reimbursements are our compensation to you and your child in recognition of your time and effort. We will reimburse you for any other reasonable out-of-pocket expenses for being in this study at your request.

Conflict of Interest

None of the people involved in this study have a conflict of interest. This means that they will not benefit personally or financially from this study.

Consent

By signing this form, I agree that:

- 1) You have explained this study to me. You have answered all my questions.
- 2) You have explained the possible harms and benefits of this study.
- 3) I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time.
- 4) I am free now, and in the future, to ask questions about the study.
- 5) I have been told that my questionnaire responses and my child's blood test results will be kept private except as described to me.
- 6) I understand that no information about me or my child will be given to anyone (unless required by law).
- 7) I understand that publication of results from this study will not identify me or my child in any way.

We will keep a signed copy of this Consent Form for our records and we will give you a signed copy as well. If you have any questions about this study, please contact the Primary Investigator, Dr. Adeli at 416.813.8682 or khosrow.adeli@sickkids.ca or the Project Coordinator, Jennifer Pinto at 416.813.7654 ext. 2673 or jennifer.pinto@sickkids.ca. If you have any ethical concerns regarding participation in this study, please contact Research Ethics at 416.813.5718. To find out more about CALIPER across Canada, please visit the CALIPER website at www.caliperproject.ca.

I give consent for my child _____ to take part in this study.
Printed Full Name of child

Printed Full Name of parent/guardian

Signature of parent/guardian

Date

If parent/guardian does not read English:

Printed Full Name of witness

Signature of witness

Date

TO BE COMPLETED BY CALIPER TEAM MEMBER AT APPOINTMENT:

Printed Full Name of CALIPER Member who explained consent

Signature of CALIPER Member who explained consent

Date