

Parent/Guardian Consent Form

Title of Research Project

CALIPER: Canadian Laboratory Initiative on Paediatric Reference Intervals

Investigators

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Coordinators

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Purpose of the Research

CALIPER is a nation-wide initiative to create an updated database of 'paediatric reference intervals' - a range of chemistry and hematology 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 in paediatric reference intervals 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 this consent form, which will take about 10 minutes. For additional information on our project, please go to www.caliperproject.ca. You can complete the questionnaire and consent form prior to your child's participation or at the time of your child's participation, where a SickKids CALIPER team member will be available to assist you and your child. A copy of the consent form will be provided or sent to you. *If your child will be participating at a school clinic and/or you will not be accompanying your child to their appointment, please be sure to complete the questionnaire and sign this 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, please contact the Project Coordinators at 416.813.7654 ext. 202673 or caliper.project@sickkids.ca to schedule an appointment for your child. It is NOT necessary for children to fast for this study. However, if your child decides to fast, the fasting period will depend on their age (4–6 hours after last meal for children 2–12 years old and a minimum of 8 hours after last meal for children 13–18 years old).

Step 3: Day of Your Child's Appointment

Upon arrival, you and/or your child will be greeted by a CALIPER team member who will review the details of the project with you and/or your child and can also help you and/or your child 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. The CALIPER team member will ask you and/or 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, they may be asked to complete a Tanner form, which is a measure of pubertal development. A SickKids phlebotomist experienced with paediatric blood collection will then take a one-time small blood sample from your child's arm, which takes approximately 3 minutes. Sample collection will take place in a secure and safe environment with all necessary materials. Depending on the age, the amount of blood taken will be as follows: 0–12 months, 1–2 mL; 1–10 years, 3–6 mL; 11–18 years, 6–11 mL. No other visits or additional tests will be needed.

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

We will share your child's test results that could be of concern with your child's doctor. Your child's doctor can then share these results with you.

Participation

Participation in this study is voluntary. If you choose to let your child take part in this study, you can opt your child out of the study at any time during participation. If you choose to have your child's sample withdrawn from the study after participation, we can remove the biological sample from the Biobank only if it has not been tested and used as part of our findings. If, in fact, your child's sample has been tested and been used for our study, withdrawing the sample and/or other information is not possible at that 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. You will be notified if there are any changes made to the study that would affect your decision to have your child participate in the study. In that case, we will ask for your consent again if you still want your child to be in the study. If your child becomes ill or is harmed because of study participation, we will treat your child. 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) and the Canadian Institutes of Health Research.

Potential Benefits to Participants

In addition to knowing one has helped children and teens with medical concerns across Canada, participants themselves (and/or a 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 3 minutes). Depending on the child's comfort level, it can sometimes take a little longer.

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 a school). Total participation time, excluding travel to and from your child's appointment, will be approximately 15 minutes.

Confidentiality

We will respect your privacy. All data is strictly confidential and will be used only for this research project and our collaborative studies. 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. All information that is published is completely anonymous. 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 Research Ethics Board and Research Quality and Risk Management teams, and other collaborating CALIPER sites, or the regulator of the study may see your questionnaire responses or your child's test results to check on the study. By signing this consent form, you agree to let these people look at this information.

Upon participation, your child's study forms and biological samples will be coded with a CALIPER ID. This is used to protect the confidentiality of your child's information. All identified information (DOB, contact information) will be kept from de-identified information and biological samples. All information shared with other sites and collaborating organizations will only be de-identified data to protect your child's identity.

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. Your child's sample will be kept until the completion of all CALIPER studies and then destroyed as required by SickKids policy. During this time, your child's sample will be stored in a Biobank located at SickKids Hospital, under double lock, de-identified. Published study results will not reveal your identity or your child's identity. De-identified samples may be sent to other locations for analysis and testing, such as other CALIPER sites or collaborating organizations. By signing this consent form, you agree to have your child's sample stored in a Biobank and sent off-site for analysis.

Reimbursement

Each participant will receive the following for donating:

- \$10 for blood donation
- two volunteer hours
- choice of t-shirt or teddy bear

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 research consent form, I understand and confirm that:

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I allow access to my child's biological samples as explained in this consent form,
4. I do not give up any of my legal rights by signing this consent form,
5. I understand that my child's family doctor/health care provider may be informed of my participation in this study,
6. I have been told I will be given a signed and dated copy of this consent form.

We will keep a signed copy of this Consent Form for our records and will provide or send you a 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 Coordinators at 416.813.7654 ext. 202673 or caliper.project@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.

Please complete this page if your child will be taking part in this study:

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

To be completed by parent/guardian:

Please check the appropriate box(es):

My child will be donating a blood sample today. Parent/Guardian Signature: _____

Printed Full Name of Parent/Guardian Parent/Guardian Signature Date & Time

If parent/guardian does not read English:

Printed Full Name of Witness Witness Signature Date & Time

TO BE SIGNED BY CALIPER TEAM MEMBER TO ENSURE COMPLETED QUESTIONNAIRE AND SIGNED CONSENT:

Printed Full Name of CALIPER Team Member who explained consent

Signature

Date