

Participant Consent Form

Title of Research Project

CALIPER: Canadian Laboratory Initiative on Paediatric Reference Intervals

Investigators

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Coordinator

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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 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 (enclosed) 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 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. A copy of the consent form will be provided or sent to you. *If you will be participating at a school clinic and if you will please be sure to complete the questionnaire and sign this consent form before your appointment.*

Step 2: Schedule Your Appointment

If you will be participating at a school clinic, your school will schedule your appointment. If you will be participating at SickKids or at a nearby CALIPER site, please contact the Project Coordinator, Giulia Fabiano at 416.813.7654 ext. 202673 to schedule an appointment for you. It is NOT necessary to fast for this study. However, if you decide to fast, the fasting period will depend on your age (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 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. The CALIPER team member will ask you a few questions (e.g. your recent diet and exercise) and take a few measurements (e.g. your height, waist and weight). If you are between 8-15 years old, you may be asked to complete a Tanner form, which is a measure of your pubertal development. A SickKids phlebotomist experienced with paediatric blood collection will then take a one-time small blood sample from your arm, which takes approximately 3 minutes. Sample collection will take place in a secure and safe environment with all necessary materials. Depending on your age, the amount of blood taken will be as follows: 1 blood collection tube; 1-10 years, 2 blood collection tubes, 11-18 years, 3 blood collection tubes. No other visits or additional tests will be needed.

Step 4: Follow-up with Your Doctor

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

Participation

Participation in this study is voluntary. If you choose to take part in this study you can opt out of the study at any time during participation. If you choose to have your 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 sample has been tested and been used for our study, withdrawing the sample and/ or other information is not possible at that time. If you should ever need care at SickKids, this will not be affected in any way by whether you take 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 to be in the study. If you become ill or are harmed because of study participation, we will treat you. You 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 Canadian Institute for 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 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 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 your comfort level, it can sometimes take a little longer.

Potential Discomforts or Inconvenience

Your 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 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 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 test results to check on the study. By signing this consent form, you agree to let these people look at this information.

Upon check in, your personal information on the questionnaire and biological samples will be coded with a CALIPER ID. This is used to protect the confidentiality of your information. All identified information (DOB, contact information) will be kept separately in a secured location. All information shared with other sites and collaborating organizations will only have access to information that is coded to protect your 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 sample will be kept until the completion of all CALIPER studies, and then destroyed as required by SickKids policy. During this time, your sample will be stored in a Biobank located at SickKids Hospital, under double lock, de-identified. Published study results will not reveal your 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 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 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 (if any) of this study.
- 3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at Sick Kids.
- 4) I am free now, and in the future, to ask questions about the study.
- 5) I have been told that my study records will be kept private except as described to me.
- 6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
- 7) I have read and understood pages 1 to 3 of this consent form. I agree, or consent, to take part in this study.

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, the Project Coordinator, Giulia Fabiano at 416.813.7654 ext. 202673 and ext. 228994. 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.

