

Participant/Teen Consent Form
For participants/teens who are 16 to 18 years old

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 blood test results obtained from a group of healthy children and teens to determine what is normal when a child or teen with medical concerns is screened for a disease. Your blood sample will help to fill in the critical gaps that currently exist with respect to age, gender, and ethnicity. This in turn will help to improve assessment and treatment of children and teens 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 appointment, where a SickKids CALIPER team member will be available to assist you. Upon request, a hard copy can be mailed to you.

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 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. Fasting is optional for this study. If you decide to fast, we ask that you do not eat for a minimum of 8 hours before your appointment (ideally before breakfast).

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 explain the blood donation procedure to you. You and the CALIPER team member will then sign this 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). An experienced phlebotomist will then take a one-time small blood sample from your arm, which will take about 5 minutes. You will be asked to complete a Tanner form, which is a measure of pubertal development. No other visits or additional tests will be needed.

Step 4: Follow-up with Your Doctor

We will share your blood test results that could be of concern with your doctor (and also normal blood test results if you wish). Your doctor can then share these results with you.

Sponsorship

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

Participation

Participation in this study is voluntary. If you choose to take part in this study you can withdraw from the study at any 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. 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 you become ill or harmed because of study participation, we will treat you 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.

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 or teen 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 5 minutes). While the amount of blood that will be collected is small, the impact that it will have in terms of helping children and teens with medical concerns is immeasurable.

Potential Discomforts or Inconvenience

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

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.

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 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.

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 take part in the study. I also have the right to withdraw from 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 blood test results will be kept private except as described to me.
- 6) I understand that no information about me will be given to anyone (unless required by law).
- 7) I understand that publication of results from this study will not identify me 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 _____ consent to take part in this study.

Printed Full Name of participant

Printed Full Name of participant

Signature of participant

Date

If participant 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