



Dear Medics Camp Children and Families,

The Hospital for Sick Children would like to share a great opportunity with children and families at Medics Camp. SickKids and the CALIPER program (www.caliperproject.ca) have launched a pediatric COVID-19 study in the GTA. Our central goal is to support children and parents across the GTA by surveying children and adolescents for COVID-19 exposure through testing for **viral antigen** (current infection, nasal sample) and **antibody** (past exposure/vaccination, blood sample).

COVID-19 Study: Participation in the COVID-19 study would involve attending a Medics Camp clinic and:

1. Complete informed consent
2. Complete health questionnaire
3. Provide a nasal swab (rapid test) AND/OR a small blood donation (~1 tsp, antibody test)

Participation is completely voluntary and open to all interested students, with the option to participate in only one or both tests. Test results will be returned to student's parent/guardian in a timely manner at no cost.

CALIPER Healthy Children Study: You and your child can also contribute to SickKids by providing permission to use blood samples collected for COVID-19 testing for additional testing of markers of health and disease. This will help SickKids improve diagnosis of students with medical concerns. No additional samples will be collected. Participation only requires completion of a second consent form. As a thank you for participating in the CALIPER study, students will receive a CALIPER t-shirt, \$10, and 2 community service hours.

If you are interested in joining SickKids in the fight against COVID-19 and participating in either study, please select the options below and complete and return the appended forms before your scheduled clinic date on a Friday during Medics Camp.

- ☐ Pediatric COVID-19 Seroprevalence Study (see forms printed in white)
- ☐ SickKids CALIPER Program (see forms printed in blue)

Thank you for your consideration and support! Please email us with any questions. We look forward to seeing you on **Fridays from July 15th to August 19th**. A virtual information session will also be hosted beforehand – keep your eye out for more information!

Best Regards,

Dr. Khosrow Adeli

Principal Investigator, CALIPER Initiative
Paediatric Laboratory Medicine
The Hospital for Sick Children
555 University Avenue | Toronto, ON, Canada
Phone: (416) 813 8682 | Fax: (416) 813 6257
Email: khosrow.adeli@sickkids.ca

CALIPER Team

Phone: (416) 813-7654 X202673
Email: caliper.project@sickkids.ca

Participant Contact Information

Please Note: We may contact you if your responses need to be clarified.

Please complete this form to the best of your ability; however, you may skip any questions you are uncomfortable answering.

Today's Date (Month-Day-Year)	Clinic Location:
Participant's Name (First) _____ (Last) _____	Participant's E-Mail Address:
Mailing Address:	
Are you interested in being contacted to participate in this study again in the future? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Emergency Contact Name (First) _____ (Last) _____	Phone Number:
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Participant's Doctor's Name Dr. (First) _____ (Last) _____	Phone Number:
Mailing Address:	

FOR OFFICE USE ONLY

Items Included Participant's File	Database Information	Missing Information
<input type="checkbox"/> Questionnaire <input type="checkbox"/> Participant Consent <input type="checkbox"/> Informed Consent Discussion <input type="checkbox"/> Blood Requisition Form Filed By: (Name) _____ (Date) _____	Entered Into Database? <input type="checkbox"/> Yes. Database Name: _____ Entered By: (Name) _____ (Date) _____ Database Verified? <input type="checkbox"/> Yes. Verified By: (Name) _____ (Date) _____	Outline Missing Information Here: Resolved By: (Name) _____ (Date) _____

SickKids COVID-19 Seroprevalence Study

Pediatric Study Questionnaire

Today's Date (DD/MM/YYYY)	Partial Date of Birth (MM/YYYY)
Please provide your biological sex: <i>(Please Note: This question is asking your biological sex, not gender identity)</i> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Intersex <input type="checkbox"/> Prefer not to answer </div>	
Have you participated in this initiative before? <div style="margin-top: 5px;"> <input type="checkbox"/> Yes <input type="checkbox"/> No </div>	
Maternal ethnicity: <div style="margin-top: 5px;"> <input type="checkbox"/> White <input type="checkbox"/> South Asian <input type="checkbox"/> Chinese <input type="checkbox"/> Black <input type="checkbox"/> Filipino <input type="checkbox"/> Latin American <input type="checkbox"/> Arab <input type="checkbox"/> Southeast Asian <input type="checkbox"/> West Asian <input type="checkbox"/> Korean <input type="checkbox"/> Japanese <input type="checkbox"/> Prefer to specify: _____ <input type="checkbox"/> Prefer not to answer <input type="checkbox"/> Unknown </div>	Paternal ethnicity: <div style="margin-top: 5px;"> <input type="checkbox"/> White <input type="checkbox"/> South Asian <input type="checkbox"/> Chinese <input type="checkbox"/> Black <input type="checkbox"/> Filipino <input type="checkbox"/> Latin American <input type="checkbox"/> Arab <input type="checkbox"/> Southeast Asian <input type="checkbox"/> West Asian <input type="checkbox"/> Korean <input type="checkbox"/> Japanese <input type="checkbox"/> Prefer to specify: _____ <input type="checkbox"/> Prefer not to answer <input type="checkbox"/> Unknown </div>

1. Health Information:

(a) Do you have a diagnosed health condition or a long-term illness?

- ☐ No
☐ Yes – Please Explain:
-

(b) Do you regularly take any prescribed medication(s)?

- ☐ No
☐ Yes – Please Indicate Medication(s):
-

(c) Have you been ill within the past 7 days?

- ☐ No
☐ Yes – Please Explain:
-

(d) Have you had any of the following symptoms in the past 7 days?

- ☐ Cough
☐ Fever
☐ Shortness of breath
☐ Headache
☐ Sore throat
☐ Diarrhea
☐ Decreased sense of smell
☐ None

(e) Please indicate ALL prescribed medications you have taken in the past 2 weeks?

- ☐ No Prescribed Medications Have Been Taken in The Past 2 Weeks
☐ Anxiety/Depression Medication
☐ ADHD/ADD Medication
☐ Birth Control
☐ Asthma Medication
☐ **Other** – Please Explain:
-

(f) Please indicate ALL non-prescribed medications or substances you have taken in the past 2 weeks.

- ☐ No Non-Prescribed Medications or Substances Have Been Taken in The Past 2 Weeks
☐ Cold or Flu Medications (e.g. Tylenol Cold, Cough and Flu, Decongestants, Cough Syrup, etc.)
☐ Ibuprofen (Advil) / Acetaminophen (Tylenol) / Acetylsalicylic Acid (Aspirin)
☐ Allergy Medication (Antihistamines – e.g. Benadryl, Reactine, etc.)
☐ Other (e.g. Cigarettes, Alcohol, Recreational Drugs, etc.) – Please Explain:
-

(g) Did you get a flu shot in the past year?

- ☐ Yes
☐ No
☐ Prefer not to answer

(h) What is your current weight? _____

(i) What is your current height? _____

2. Household Information

(a) How many people live in your household? _____

(b) How many bedrooms are in your household? _____

(c) How many bathrooms are in your household? _____

3. SARS-CoV-2 Exposure Information

(a) Have you ever been tested for COVID-19 by nasal/throat swab?

- ☐ Yes
☐ No

(b) How many times have you been tested for COVID-19 by nasal/throat swab?

- ☐ 0
☐ 1
☐ 2
☐ 3
☐ 4+

(c) Please provide your testing history.

Test Number:	Date of Test:	Result:
First Test (if applicable)	_____/_____/_____ EARLY/ MID/LATE MO YR	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown
Second Test (if applicable)	_____/_____/_____ EARLY/ MID/LATE MO YR	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown
Third Test (if applicable)	_____/_____/_____ EARLY/ MID/LATE MO YR	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown
Fourth Test (if applicable)	_____/_____/_____ EARLY/ MID/LATE MO YR	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown

(d) Did you have any of the following symptoms between January 2020 and present?

- ☐ Cough
- ☐ Fever
- ☐ Shortness of breath
- ☐ Headache
- ☐ Sore throat
- ☐ Diarrhea
- ☐ Decreased sense of smell
- ☐ Other symptoms. Please specify: _____
- ☐ None

(e) Have you ever been hospitalized for COVID-19?

- ☐ Yes
- ☐ No

(f) Have you travelled outside of Canada since January 2020?

- ☐ Yes. Please specify: _____
- ☐ No

(g) Have you lived with anyone in the following occupations since January 2020?

- ☐ Hospital or health care facility worker
- ☐ First responder (paramedic, firefighter, police officer)
- ☐ Childcare worker
- ☐ Correctional officer
- ☐ Teacher/other school staff
- ☐ Transit driver
- ☐ Food service industry
- ☐ Grocery store
- ☐ Pharmacy
- ☐ Hairdresser/barber
- ☐ Aesthetician
- ☐ Flight attendant
- ☐ Factory worker
- ☐ None

(h) Have you been sent home from school due to a positive COVID-19 case since September 2020?

- ☐ Yes
- ☐ No

(i) Have you received a COVID-19 vaccine?

- ☐ Yes
 - Please provide type of vaccine (e.g. Pfizer, Moderna): _____
 - Date of first dose: _____
 - Date of second dose: _____
 - Date of third dose: _____
- ☐ No

Consent to Participate in a Research Study
Parental Consent for Child

Study Title: SickKids COVID-19 Seroprevalence Study

Principal Investigator:

Dr. Khosrow Adeli, Department of Paediatric Laboratory Medicine, 416.813.8682

Co-investigator(s):

Dr. Aaron Campigotto, Department of Paediatric Laboratory Medicine

Dr. Michelle Science, Department of Infection Control

Study Team/Research Contact:

Mary Kathryn Bohn, Department of Paediatric Laboratory Medicine, 416.813.7654 ext. 202673

Study Sponsor and/or Funder:

- The Hospital For Sick Children
- Merck Canada Inc.
- Abbott Laboratories

Conflict of Interest:

There are no conflicts of interest to declare related to this study.

Introduction

Your child is being invited to take part in our research study. This consent form describes the research study and what it means to participate. This consent form may have words that you do not understand. Please ask the study staff to explain anything that you do not understand. Please take as much time as you need to think about your decision to allow your child to participate or not, and ask any questions you have. If it is helpful to you, you are encouraged to discuss the study with family, friends, your child's personal physician, other health professionals, or any members of your community that you trust. All participation in a research study is voluntary and you are not under any obligation to allow your child to participate.

Why is my child being asked to participate?

Your child is being invited to participate in this study because they are a child who lives in Southern Ontario.

Why is this study being done?

Understanding how COVID-19 affects children is an essential part of public health and education decisions! This seroprevalence study aims to assess COVID-19 prevalence in children in the Toronto area through viral and antibody testing.

How many participants will be in this study?

This study is being done at SickKids only. We expect to enroll up to 2200 children and adolescents in this study from various recruitment centres throughout southern Ontario.



What will happen in this research study?

Your child's participation is expected to take around 20 minutes. If your child indicated that they are interested in participating more than once on the contact information form, the research team will contact you by phone to update you on upcoming clinic events. Consent will be completed at each time.

Your child's participation will involve the completion of a health questionnaire, which will take about 5 minutes to complete. The questionnaire asks about your child's health status and other demographic factors. The questionnaire can be completed individually or with the study team if you have questions.

Your child's participation will also involve donation of a small blood sample and/or nasal and saliva sample at a clinic near you, as described below.

What samples will be collected as part of this study?

Your child's participation will involve donation of a small blood sample (7 mL, 1 tsp) **AND/OR** nasal and saliva sample (1-2 mL) at a clinic near you. If your child donates a **nasal sample**, a rapid antigen test will be used to identify current COVID-19 infection. Your child will be notified if their result is positive within two hours of participation. A **saliva sample** (1-2 mL) will also be collected to confirm COVID-19 test results at SickKids Laboratory in the case of a positive result. If your child donates a **blood sample**, an antibody test will be used to identify past COVID-19 infection as well as immune response to infection or vaccination. Participants have the option to participate in only one or all tests.

Please initial next to your preference:

Options	Initial
You can collect a blood sample only from my child to identify past SARS-CoV-2 exposure (antibody testing).	<hr/>
You can collect a nasal and saliva sample only from my child to identify current SARS-CoV-2 infection (rapid antigen and confirmation testing).	<hr/>
You can collect a blood, nasal AND saliva sample from my child to perform all tests.	<hr/>

To protect your child's identity, the information that will be on your child's samples will be limited to a study ID that is only able to be linked to your child's personal information by the study team. Despite protections being in place, there is a risk of unintentional release of information. Once the tests required for the study have been completed, any leftover samples will be stored for 5 years for retesting purposes and then destroyed.

What are the risks, harms or discomforts of the study?

Your child may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not known or expected. You should tell the study doctor if your child has any complaints, behavior changes, changes to their health, or had other doctor visits or hospitalizations outside of the study visits. It is important that you discuss these with the study doctor.



There is a possibility of pain, bruising, swelling or infection related to the blood draw. There may also be some discomfort when taking a nasal sample. These discomforts are minimal and brief.

There is an inconvenience of time. Participation will take about 20 minutes.

Despite protections being in place, there is a risk of unintentional release of information. Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated.

Are there benefits from being in the study?

Your child may not directly benefit from being in this study. However, the information we learn from this study will be used to improve our understanding of how COVID-19 affects children. You will also receive your child's test results in a timely manner.

What are my responsibilities in this study?

If you choose to participate in this study, you will be expected to:

- Tell the study doctor about all of your child's current medical conditions.
- Tell the study doctor about all your child's prescription and non-prescription medications such as over-the-counter drugs, and supplements, including vitamins and herbal medications, naturopathic treatments.
- Ask your study team about anything that worries you or your child.
- Tell the study staff if you change your mind about your child being in this study.

Request to collect and store biological samples for future research

As part of this research study, the researchers at SickKids would like to ask you and your child to store your child's left over sample and/or de-identified research data from this study for use in future research studies. This research could include additional studies on COVID-19 testing or unknown research studies. This will not include genetic research. The Hospital for Sick Children will decide the type of research that is done on these samples and with whom they will share these samples for research purposes.

Sharing your child's samples and information with for-profit companies:

Sharing your child's de-identified biological samples and health information with for-profit commercial companies such as pharmaceutical companies are optional. You will be asked to provide your parental consent below.

A for-profit company may be a pharmaceutical company that wants to make a new drug or test a currently approved drug for another disease or population. It may also be a biotechnology company that develops new ways to treat or diagnose disease. If you consent for for-profit company sharing, SickKids may receive money in exchange for your samples and study information. Any funds we receive will support our new and ongoing research on COVID-19. Your child's samples and health information will be identified only by a unique ID number assigned to you.

Please initial next to your preference:

Options	Initial
Yes , you can collect my child's samples to be stored in a biobank as described above for use in future unknown research studies, along with my child's de-identified research data from this study.	<hr/>



No , you cannot collect my child's samples to be stored in a biobank as described above for use in future unknown research studies, along with my child's de-identified research data from this study.	<hr/>
Yes , I agree for my child's samples collected in this study to be used for research purposes with commercial companies.	<hr/>
No , I do not agree for my child's samples collected in this study to be used for research purposes with commercial companies.	<hr/>

Can I choose to have my child leave the study?

It is your choice, and your child's, to decide to take part in this study, and participation is voluntary. You and your child can change your mind at any time during the research study. To not complete full participation, please let the study team know.

Can I withdraw my child's samples from the research study?

If you no longer want your child's samples to be used in this research you can request to have their samples withdrawn and destroyed. Please note that any samples that have been shared cannot be withdrawn. Biological samples collected as part of the main study can be withdrawn by contacting the study doctor and coordinators over the phone.

Can I withdraw my child's research data from the research study?

If you no longer want your child's study information to be used in this research you can request your child's data to be withdrawn and destroyed. Please note that any study data that has been included as part of the analysis or that has been shared cannot be withdrawn. If you want your child to leave the study and want to withdraw your child's de-identified information collected for the research study, let a member of the study team know.

What if the researchers discover something about my child?

All test results from your child's sample will be reported back to you or your child's primary care physician. If a positive result is determined via nasal sample, results will be confirmed through a saliva sample test and your child will be referred to the SickKids immunology clinic for further follow up. You will be asked to provide your child's family doctor's name and contact information.

Will it cost me or my child anything to be in this study?

Taking part in this study will not result in added costs to you.

Will my child be paid and/or reimbursed if they join this study?

You and/or your family will not be paid to be part of this study. We do not anticipate any additional costs to you and/or your family for participating in this research study. In recognition of your participation, your child will be given a certificate of participation.

It is possible that a commercial product may be developed as a result of this study. You and your child will have no rights to any products that may be created as a result of this study or any future research studies using this research study data. You and your child will not receive royalties from any products that may be created as a result of this study or any future research studies.



What personal health information will be collected about my child as part of this study?

Personal health information (PHI) is any information that is collected about your child from their medical records. PHI also includes any information collected from/about your child during the study. If you decide to allow your child to participate in this study, the SickKids study team (study investigators, coordinators, nurses and delegates) will collect personal health information about your child. This includes things learned from the study procedures described in this consent form and/or information from your child's medical records. The study team will only collect the information they need for this study.

Some of the data collected for this study includes identifiable information about your child, including: partial date of birth (month and year), telephone number, address, and postal code. This information is needed to know your child's age and to contact you for follow up.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your child's race or ethnic origin is voluntary.

How will my child's privacy be protected?

Your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your child's privacy is respected. We will respect your child's privacy. The Hospital for Sick Children is also committed to respecting your child's privacy. No information about your child will be given to anyone or be published without your permission, unless the law requires us to do this.

Information collected about your child will be "de-identified" by replacing your child's name with a unique participant code. Records identifying your child at SickKids (including the link between your child's identity and your child's participant code) will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

The SickKids study team is in control of the study code key, which is needed to connect your child's personal health information/personal information to them. The link between the study number and your child's identity will be safeguarded by the SickKids study staff and will not be available to the (Sponsor/Funding agency/Coordinating centre). SickKids guidelines include the following:

- All information that identifies your child, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying your child will be allowed off site in any form without your consent. Examples include your child's hospital or clinic charts, copies of any part of your child's charts, or notes made from your child's charts.

The following people may look at your child's original (identifiable) medical/study records to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of SickKids Research Ethics Board and other SickKids staff who oversee the conduct of research at SickKids



Access to your child's personal health information will take place under the supervision of the Study Doctor. You and your child have the right to access, review and request changes to your child's personal health information. The study staff and the others listed above will keep the information they see or receive about your child confidential, to the extent permitted by applicable laws. Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated.

The study staff will keep any personal health information about your child in a secure and confidential location for 5 years and then destroy it according to SickKids policy. When the results of this study are published, your child's identity will not be disclosed. You and your child have the right to be informed of the results of this study once the entire study is complete. You also have the right to request for your child's study information to be sent to you and/or another person such as your treating doctor, a member of your health care team, or a family member. You can choose the way by which this information is requested. For example, you can have the information sent to you or any person you wish to have this information sent in paper or electronic format.

De-identified study data will be transferred to Mount Sinai Hospital. Study data is being shared so that study doctor can complete specialized testing.

In some cases, your rights to your child's information may be limited by current rules and laws related to the use and storage of information collected as part of a research study. This will be explained to you as needed.

If you have any concerns about the way your child's information is being kept private, you can contact the SickKids Research Ethics Board or the SickKids Privacy Office.

Will information about this study be available online?

A description of this study will be available on www.caliperproject.ca. This website will not include information that can identify your child. You and your child can search this website.

What if my child is injured during/in this study?

If your child suffers an injury from participation in this study, medical care will be provided to your child in the same manner that they would ordinarily obtain any other medical treatment. In no way does signing this consent form waive your child's legal rights or release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities. If your child requires treatment for any injuries or illness related to your child's participation in the study, you should contact the study doctor immediately.

How will my child be informed about new information?

We may learn new information during the study that you and your child may need to know. We may also learn about things that might make your child want to stop participating in the study. If this happens, you and your child will be notified about any new information in a timely manner. You and your child may also be asked to sign a new consent form that describes these new findings if you decide to continue in the research study.

Will my child receive study results?

All test results from your child's sample will be reported back to you or your child's primary care physician. If a positive result is determined via nasal sample, results will be confirmed through a saliva sample test



and your child will be referred to the SickKids immunology clinic for further follow up. You will be asked to provide your child's family doctor's name and contact information.

Research results will be shared through journal publications and academic conferences. When the results of this study are shared, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the study doctor know.

What are my child's rights when participating in a research study?

You and your child have the right to receive all information that could help you make a decision about participating in this study. You and your child also have the right to ask questions about this study at any time and to have them answered to your satisfaction. Your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your child's privacy is respected.

By signing this form, you do not give up any of your child's legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to your child's participating in this study. If your child is able to read, they will be given information about the study in a different form, called an assent form. If you agree to have your child take part in this study, and your child agrees to be in the study, your child will be asked to provide their assent to show that they understand what will happen in the study.

We may do future related research studies and want to know if we can contact you and your child about these studies in the future. Please initial next to your preference:

Initial	Options:
_____	Yes , you can contact my child regarding future related research studies.
_____	No , I do not want you to contact my child regarding future related research studies.

Who can I call if I have questions about the study?

If you have any questions during your participation in this research study you can contact the Study Doctor, Khosrow Adeli at 416.813.8682 or Mary Kathryn Bohn and/or CALIPER coordinator team at 416.813.7654 ext. 202673.

Research Ethics Board Contact Information

The study protocol and consent form have been reviewed by the SickKids Research Ethics Board (REB). If you have any questions regarding your child's rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.



Consent to Participate in a Research Study

Study Title: SickKids COVID-19 Seroprevalence Study

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 medical records and/or biological samples as explained in this consent form,
4. I do not give up any of my child's legal rights by signing this consent form,
5. I understand that my child's family doctor/health care provider(s) will/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.

I consent on behalf of _____ to participate in this study.

Printed Name of Parent/SDM

Parent/SDM signature & date
(DD/MM/YYYY)

Printed Name of person who
obtained consent

Role of person
obtaining consent

Signature & date
(DD/MM/YYYY)

Parent/Guardian Consent Form

Title of Research Project

CALIPER: Canadian Laboratory Initiative on Paediatric Reference Intervals

Investigators

Dr. Khosrow Adeli, Principal Investigator
416.813.8682

Coordinators

416.813.7654 ext. 202673
caliper.project@sickkids.ca

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 (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 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 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 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. 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 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. With your permission and if your child is between 8-15 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 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 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 Institute 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 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 check in, your child’s personal information on the questionnaire 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 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 the identity of your child.

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 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 having my child take part in this study. 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. My decision about my child taking part in the study will not affect my child's 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 child's study records will be kept private except as described to me.
- 6) I understand that no information about my child 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, that my child may take part in this study.

We will keep a signed copy of this Consent Form for our records and you will be provided or sent 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.

I have read and understood pages 1 to 3 of this consent form. I agree, or consent, that my child may take part in this study. 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 child

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

 Signature of parent/guardian

 Date & Time

If parent/guardian does not read English:

 Printed Full Name of witness

 Signature of witness

 Date & Time

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

Printed Full Name of CALIPER Member who explained consent

Signature of CALIPER Member who explained consent

Date