SickKids

Office Use Only
Participant ID #: _____

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?

- ☐ **Yes**
- ☐ **No**

Emergency Contact Name (First) (Last)	**Phone Number:**

Participant's Doctor's Name Dr. (First) (Last)	**Phone Number:**

Mailing Address:

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Items Included Participant's File	Database Information	Missing Information
☐ Questionnaire ☐ Participant Consent ☐ Informed Consent Discussion ☐ Blood Requisition Form **Filed By:** (Name) (Date)	**Entered Into Database?** ☐ **Yes**. Database Name: _____ **Entered By:** (Name) (Date) **Database Verified?** ☐ **Yes**. **Verified By:** (Name) (Date)	**Outline Missing Information Here:** **Resolved By:** (Name) (Date)

SickKids

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Participant ID #:

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:
(Please Note: This question is asking your biological sex, not gender identity)

☐ Female ☐ Male ☐ Intersex ☐ Prefer not to answer

Have you participated in this initiative before?

☐ Yes
☐ No

Maternal ethnicity:	**Paternal ethnicity:**
☐ White	☐ White
☐ South Asian	☐ South Asian
☐ Chinese	☐ Chinese
☐ Black	☐ Black
☐ Filipino	☐ Filipino
☐ Latin American	☐ Latin American
☐ Arab	☐ Arab
☐ Southeast Asian	☐ Southeast Asian
☐ West Asian	☐ West Asian
☐ Korean	☐ Korean
☐ Japanese	☐ Japanese
☐ Prefer to specify:	☐ Prefer to specify:
☐ Prefer not to answer	☐ Prefer not to answer
☐ Unknown	☐ Unknown

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 <u>past 7 days</u>?

☐ No
☐ Yes – Please Explain:

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

- ☐ 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 <u>past 2 weeks</u>.

- ☐ 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 <u>past 2 weeks</u>.

- ☐ 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

Please provide the date and result of your most recent COVID-19 nasal/throat swab.

Test Number:	Date of Test:	Result:
Most Recent Test *(if applicable)*	_____ / ___ / ___ EARLY/ MID/LATE MO YR	☐ **Negative** ☐ **Positive** ☐ **Unknown**

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

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4+

Please provide your POSITIVE testing history.

Test Number:	Date of Test:
First Test *(if applicable)*	_____ / ___ / ___ EARLY/ MID/LATE MO YR
Second Test *(if applicable)*	_____ / ___ / ___ EARLY/ MID/LATE MO YR
Third Test *(if applicable)*	_____ / ___ / ___ EARLY/ MID/LATE MO YR
Fourth Test *(if applicable)*	_____ / ___ / ___ EARLY/ MID/LATE MO YR

(c) 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

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

- ☐ Yes
- ☐ No

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

- ☐ Yes. Please specify: _____
- ☐ No

(f) Have you lived with anyone working 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

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

- ☐ Yes
- ☐ No

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

- ☐ No
- ☐ Yes, 1st dose only
- ☐ Yes, 1st and 2nd dose
- ☐ Yes, 1st, 2nd and 3rd dose
- ☐ Yes, 1st, 2nd, 3rd, and 4th dose
- ☐ Other – Please explain: _____

If yes, please provide your vaccine history.

Dose Number:	Type of Vaccine:	Date of Vaccine:
First Dose	☐ Pfizer ☐ Moderna ☐ Astrazeneca ☐ Other. Please explain: _____	MM/DD/YYYY
Second Dose	☐ Pfizer ☐ Moderna ☐ Astrazeneca ☐ Other. Please explain: _____	MM/DD/YYYY
Third Dose	☐ Pfizer ☐ Moderna ☐ Astrazeneca ☐ Other. Please explain: _____	MM/DD/YYYY
Fourth Dose	☐ Pfizer ☐ Moderna ☐ Astrazeneca ☐ Other. Please explain: _____	MM/DD/YYYY

SickKids

Office Use Only
REB #:

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 ONCE 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).	
You can collect a **nasal and saliva sample only** from my child to identify current SARS-CoV-2 infection (rapid antigen and confirmation testing).	
You can collect a **blood, nasal AND saliva sample** from my child to perform all tests.	

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 ONCE 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.	
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.	

Please initial ONCE next to your preference:

Options	Initial
Yes, I **agree** for my child's samples collected in this study to be used for research purposes with commercial companies.	
No, I do **not agree** for my child's samples collected in this study to be used for research purposes with commercial companies.	

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 <u>if we can contact you and your child</u> about these studies in the future. Please initial ONCE next to your preference:

Options	**Initial**
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)