PARTICIPANT CONSENT & INFORMATION SHEET

Title of Study: COVID CommUNITY Study

Locally Responsible Investigator and Principal Investigator: Dr. Sonia Anand, Professor of Medicine, Population Heath Research Institute, McMaster University, Faculty of Health Sciences

Co-Investigator(s), Department/Hospital/Institution: (Listing of Co-Investigator(s) is optional): Dr. Russ DeSouza; Dr. Gita Wahi; Dr. Zubin Punthakee; Dr. Rahul Chanchlani; Dr. Diana Sherifali; Dr. Scott Lear; Dr. Mark Loeb; Dawn Bowdish, PhD; Dr. Shelly Bolotin; Shrikant Bangdiwala, PhD

Sponsor: Population Health Research Institute

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family.

You are being invited to participate in a research study conducted by Dr. Sonia Anand and team as part of the COVID CommUNITY study.

WHY IS THIS RESEARCH BEING DONE?

People who originate from the Indian subcontinent known as South Asians are the fastest growing group of non-white Canadians. During the COVID-19 pandemic South Asians in the United Kingdom and Canada were reported to have higher infection rate and worse outcomes after COVID-19 infection compared to white Caucasians. It is unclear whether these differences reflect biological differences, differences in social/economic factors, or differences in access and uptake of health care resources. We have an opportunity to provide much needed health information regarding COVID-19 in the South Asian population.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the COVID CommUNITY study is to determine the following among South Asians living in the Greater Toronto Hamilton Area in Ontario, and the Greater Vancouver Area, British Columbia:

1. How many people develop COVID-19 infections
2. Percentage of participants who have been offered and/or received a COVID-19 vaccine
3. The percentage of community members who are hesitant to take the COVID-19 vaccine
4. Your body's protective response to COVID-19 infection and/or vaccination

5. Confirm the proportion of participants who have had a severe short term side effect to COVID-19 vaccine
6. Confirm the proportion of participants who are hesitant or refuse to take the vaccine, and the underlying reasons why
7. Understand regional, socioeconomic and health factors that could affect infection and vaccine rates, including occupation type income, household density, and prevalence of other conditions that affect COVID-19 outcomes (e.g. obesity or diabetes).

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

If you agree to participate in this study, we will ask you to do the following things:

1. Review and sign this Informed Consent Form.
2. Complete questions regarding your experience with the COVID pandemic and current health status.
3. Complete at least two dry blood spot samples (described below) over 1 year.
4. Allow a member of the study team to contact you by mail, email, telephone, or social media to determine your health status for up to 1 year after the end of the study period.
5. Allow a member of the study team to contact you by mail, email, telephone, or social media to determine you long-term health status in the future.
6. Allow the study team to use your health card number and other personal health information for administrative record linkage to understand long-term effects (e.g. beyond 5 years) of COVID-19 infection and vaccination.

Visits

<u>New Participants Recruited from Vaccine/Assessment Centres</u>

Only participants identified on-site at the Vaccine/Assessment Centres will be part of this group.

1. **Before Vaccine**
    a. After consent you will have a dry blood spot sample collected on site either 1 hour before or 15 minutes after your 1st vaccine dose.
    b. You will complete the study questionnaire on-site either electronically, or on paper.

2. **After Vaccine**
    a. After the 2nd dose of the vaccine, a second dry blood spot sample will be collected.*
    b. You will be followed up electronically/telephone to determine if you have developed COVID-19, or have been hospitalized for a vaccine related side effect. You will complete an additional questionnaire either electronically or by telephone, regarding your thoughts on the vaccine experience.
    *Note : This schedule may be slightly altered when one dose vaccines become available

<u>Re-contacting Existing Study Participants</u>

Participants contacted by phone or email for their interest to participate in the study will be part of this group. Consent will be completed electronically, verbally or by mail. Individuals are invited to participate regardless if they intend to receive a COVID-19 vaccine or not.

1. **Baseline**

a. You will be contacted by the study office. After consent, a dry blood spot sample collection kit will be mailed to you.
c. You will complete the dry blood spot sample collection at home and will mail the completed kit to the study office. You will complete the study questionnaire either electronically, or on paper.
b. Note: You may choose to meet study staff at a Vaccine Assessment Centre and complete the dry blood spot sample collection timed in accordance with your vaccine doses.

2. **Long-Term**
    a. Six to twelve months after the last vaccine dose, the study office will contact you and will mail a dry blood spot sample collection kit to you. The dry blood spot sample collection will be completed at home.
    b. You will complete the study questionnaire either electronically, or on paper at home.

For All Participants
Should you (or your child/relative) develop a SARS-CoV-2 infection fourteen (14) or more days after vaccination, you will be asked to inform the study team. We ask that you consider providing consent to COVID CommUNITY to re-contacting you and your health care provider to determine the strain of the virus that caused your infection (regular SARS-CoV-2 or a variant). You will be asked to consent to provide a blood sample (up to 30mL), if possible, to study how your immune system responded to the vaccination and to try to determine why you were susceptible to infection. We may contact you for a repeat blood sample (30 days/3 months/6 months/12 months) after the first blood sample. This is your decision whether or not to participate in this part of the study.

The dry blood spot samples will be used for research purpose as described above and for future related research.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
Drawing blood from a finger stick may, in rare cases, cause discomfort, bruising, prolonged bleeding and infection at the site of puncture. To minimize risk, please follow the instructions provided to you with the dry blood spot sample collection kit and only use the materials provided by the study team.

There is an extremely remote possibility of loss of confidentiality of participants' questionnaire responses. Data security features at the time of collection, data entry and for long-term storage will be used to maximize confidentiality.

If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.

HOW MANY PEOPLE WILL BE IN THIS STUDY?
Up to 4000 individuals will be a part of this study, from Ontario and British Columbia (South Asians).

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?
We cannot promise any personal benefits to you from your participation in this study. If you agree you will be provided with a one-page description of your cardiovascular risk factor profile at the end of the study . Individual dry blood spot sample results will be used for research purposes and are not yet used consistently

as a clinical test result. Individual results are anonymized and will not be available. However, this research might benefit you indirectly, as we will provide aggregate data to each community which will include their community profile regarding all aspects of this data collection. This may help inform policy development and preventive practices regarding COVID-19. Participating in this study does not restrict you participation in another study.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

It is important for you to know that you can choose not to take part in the study. If you choose not to participate in this study, you can access COVID-19 information from other sources like your local public health. Choosing not to participate in this study will in no way affect any other aspect of your life.

Choosing not to participate in this study will in no way affect your care or treatment related to COVID-19 vaccination or infection.

WHAT INFORMATION WILL BE KEPT PRIVATE?

Your data will not be shared with anyone except with your consent or as required by law. All personal information such as your name, address, phone number, and Health Card Number will be collected separately and will be kept separate from the other data which will be stored under a unique identification number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed will be securely stored on a secure server. The data and specimen for this research study will be retained until they no longer hold scientific value.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board may consult your research data. However, your confidentiality will be maintained if this occurs. By signing this consent form, you authorize such access.

Personal health information including your health card number will be shared with the Institute for Clinical Evaluative Sciences (IC/ES) in Toronto, Ontario. IC/ES is a research institute specializing in linking together health care databases and maintains strict patient confidentiality in a very secure environment. The data will be securely transferred to IC/ES and linked together with Ontario administrative health care databases to create a centralized linked database which will be held at IC/ES. All linked data will be securely coded by IC/ES to maintain participant confidentiality prior to data analysis which removes any identifying information. The data will be used to analyze and evaluate your usage of health care services (such as hospitalizations) in Ontario. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

Key data elements may need to be shared with the COVID Immunity Task Force (CITF) in an anonymized fashion to support policy development.

CAN PARTICIPATION IN THE STUDY END EARLY?

If you agree to participate in this study, you may withdraw at any time. In such case, study personnel will review various options with you to help you make an informed decision for your future with the study. However, information provided up to the point where you discontinue will be retained. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?
We will provide a token of appreciation in the form of a gift card, for participation in this study, and completion of study related activities.

WILL THERE BE ANY COSTS?
Your participation in this research project will not involve any additional costs to you.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?
If you suffer an injury from participation in this study, medical care will be made available to you by your study doctor, or you will be referred for appropriate medical care. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?
If you have any questions about the research now or later, please contact the research office of Dr. Sonia Anand at 905- 527-4322 x 40378.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Integrated Research Ethics Board at 905-521-2100, ext. 42013.

Optional Consent

I agree to be contacted for potential participation in future research studies	YES/NO	_____(initial)
I agree to allow my Health Card Number to be used for record linkage	YES/NO	_____(initial)
I would like to receive my INTERHEART cardiac risk score	YES/NO	_____(initial)
I agree to be contacted to participate in a follow up study if I contract COVID-19 during the course of this study	YES/NO	_____(initial)

CONSENT STATEMENT

Participant: (*required for participants capable of consent)*

I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	Signature	Date

Person obtaining consent: (*required for all studies)*

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	Signature	Date

Witness: *(required if participants are unable to read, or if translation is necessary)*

I was present when the information in this form was explained and discussed with the participant. I believe the participant understands what is involved in this study.

Name	Signature	Date

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.