Participant Information Sheet

Principal Investigator: Professor Prabhat Jha, +1 833-TEST-ABC (1-833-837-8222), email AbcStudy@unityhealth.to

Thank you for considering participation in the Action to Beat Coronavirus (Ab-C) Study. This important study relies on Canadians to provide crucial information to understand the numbers of Canadians who have previously been infected with the virus that causes COVID-19.

The elements of the Ab-C Study are described below. Please read this carefully, and if you decide to participate, please complete the consent form online at (www.abcstudy.ca) using your secure code printed on the consent card. Please do not share this code with anyone.

INTRODUCTION

The reason we are conducting the study is because we do not know how many people in Canada have ever been infected with the virus that causes COVID-19, information critical to planning the best public health response to the virus now and in the future. To find this out, we are asking a random sample of Canadians about any recent COVID-19 symptoms, and then asking those who agree to take a small fingerprick of blood, blot it onto filter paper, and send that to a central lab for testing to see who has been infected in the past with the virus that causes COVID-19. We know that many people who are infected never show any symptoms.

WHY IS THIS STUDY BEING DONE?
The overall goal of the Ab-C is to provide crucial information on how common the COVID-19 infection is, and to thus improve the public health response to the outbreak. The biological data may help improve the well-being of Canadians.

WHAT WILL HAPPEN DURING THE STUDY?
You have already completed the online survey for Angus Reid and are part of their panel. We used that data to understand who would be a good candidate for this study and to provide a basis for this study. Home blood collection is the next step. Each blood spot will be analyzed using validated laboratory tests to determine whether antibodies to the COVID-19 virus are present. Participants will be given the option of receiving their results (see below).

Ab-C participants have the option to provide their provincial health card number so that the information contained in provincial health databases (e.g., billings for visits to doctors, hospital admissions, medication prescriptions, etc.) can be linked to study data.

With your permission, we will also store any unused blood samples to answer questions about COVID-19 in the future. We do not yet know which factors might be examined, as research on COVID-19 is still emerging, but this future work will be done entirely anonymously, without any linkage to your identity. Any future testing on the samples will be done only for research purposes, and you will not be given its results. You will be given the results of the antibody test, as described below.

Since we do not know how long COVID-19 will exist, we will keep your identifiable information and biological samples and will link to provincial and federal health databases until we have exhausted all uses related to COVID-19.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
It is anticipated that about 10-14,000 adults aged 18 or older in Canada will participate in this study.

WHAT ARE THE RESPONSIBILITIES OF THE STUDY PARTICIPANTS?
You have already completed the Angus Reid poll, for which we thank you. You will now be asked to take a small sample of blood using safe, well-tested procedures (some diabetic patients do this at home every day) and then send us the sample in a safe, tamper proof postage-paid envelope and fill in your consent online at www.abcstudy.ca using the secure code printed on your consent card.

We will return the results of the test to you via email. If you received a COVID vaccine before taking the blood sample, the results typically indicate a “highly likely” OR “unlikely” antibody response to the vaccination. If you were unvaccinated, the results will tell you whether it is “highly likely” that you were infected in the past, OR “somewhat likely” that you were infected, OR “unlikely” that you were infected. We will not be able to tell you when or how you may have been infected.

Please note that the results are not to be used for any clinical decisions and do not prove that you have immunity to COVID-19. These results should not be used for any clinical decisions, and do not suggest, for example, that you are “immune” to the virus. Every Canadian will need to continue following federal and public health guidelines on how to protect themselves from COVID-19 and how to protect others in case one is exposed or infected.

When we contact you with the results, we will ask you for permission to re-contact you at least once in the future, to possibly re-test using the same procedures to find out if your infection status might have changed.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?
There are no medical risks to you from participating in this study. However, you may experience very minor discomfort on your finger when you do the fingerprick. The lancet used to make the small hole in your skin cannot be reused. The needle is sharp, so be careful with it around others, especially children; and we recommend that all this testing be done away from others. COVID-19 is NOT

transmitted through blood (only through lung or breathing droplets) so there is virtually no risk that anyone else in the house who may touch your blood will be at risk from COVID-19, should you be infected. However, other infections can be spread through blood so you should make sure that no one else touches your blood drop during the testing or when it is drying. Please make sure that you do the test safely and away from others, and apply the gauze for 10 minutes until all bleeding stops before you resume any normal activities.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
You will not benefit directly from participating in this study. The tests for those infected in the past are only for research purposes. This means that these test results are not diagnostic and are not designed to replace routine clinical care.

Participating in the Ab-C Study does not replace the Canadian government guidelines for COVID-19 reporting and testing. If you have any symptoms suggestive of COVID-19, then isolate yourself, take self-assessment at https://ca.thrive.health/covid19/en.

Although you will not benefit directly from participating in this study, your participation will be crucial for fighting this extraordinary epidemic which has affected the lives of so many around the world. This research will play a key role in helping to shape the public health and control responses to COVID-19 in Canada and internationally.

CAN PARTICIPATION IN THIS STUDY END EARLY?
You can choose to end your participation at any time without having to provide a reason. However, if you choose to end your participation before completing the study, you will still be asked to send the home kit unused back to the study centre using the postage-paid envelope provided.

If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. If you withdraw voluntarily from the study, you are encouraged to contact the study coordinator at 1 833-837-8222 or AbCstudy@unityhealth.to. If you withdraw your consent, the information that was/were collected before you left the study will still be used. If you wish your sample to be destroyed, you can notify us. No new information about you will be collected and no further testing will be done without your permission.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?
Participation in this study will not involve additional costs to you. You will not need to come to any study centre. All study procedures will happen in your home. All materials will be sent to you by mail, and the return mailing envelope will be postage paid.

AM I PAID TO PARTICIPATE?
No payment is made by the Ab-C team. Angus Reid organization will provide "Points" through their existing program.

WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?
If you become sick or injured as a direct result of your participation in this study, medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is very rare and not routinely available. By signing this consent form, you do not give up any of your legal rights.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?
You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?
The investigators have no conflicts of interest related to this study.

How did Ab-C get my contact information?
The Ab-C got your contact information from the Angus Reid Forum with whom the Ab-C team is partnering to conduct this vital research. During the Angus Reid Forum polling about experiences with COVID-19 you provided consent for the Ab-C team to contact you. They transferred your contact details to us using a secure network connection (called a Virtual Private Network, or VPN) to which no others had access. Also, some of you contacted us directly to participate in the Ab-C study and provided your information.

How is my privacy and confidentiality protected?
The Ab-C Study considers the public to be its most valuable partner in research. Thus, protecting your privacy and meeting your expectations in this regard is a priority at all stages of the study. The Ab-C Study team, the different institutions involved, and the Ab-C researchers and staff are all committed to ensuring that your privacy and confidentiality are always respected. We have developed a privacy policy that is consistent with guidelines by the Canadian Institute of Health Research, our hospital's Research Ethics Board and other approved studies in Canada.

Several mechanisms are in place to ensure confidentially. The most important are:

- The collected data are stored using a unique code and not your name or other identifying information. The identifying information

is stored at St. Michael's Hospital (SMH) in a secure and separate database.

- When data are collected from you, the data are automatically encrypted and transmitted with the unique ID number through a secure VPN to the central database at SMH.
- All staff involved in Ab-C are bound by a strict confidentiality agreement that prohibits them from using any information for any other purpose than what is required for their specific tasks. We maintain a log of dates and times that personnel access the identifiers.
- Data and samples are stored in highly controlled access areas where only special card holders are able to enter and a log of all entries/exits into these restricted premises is kept.
- The workstations through which the Ab-C staff are able to access the collected data (e.g., for quality control purposes) are not connected to internet, and they are password protected.
- The Ab-C will grant access only for ethically and scientifically approved future research. Approval is granted by the Ab-C Scientific Committee followed by approval from a Research Ethics Board. Approved researchers must sign confidentiality and data access agreements, which bind all users to the terms and conditions, set out by SMH. We will not release any personal or identifying information to external researchers.
- The Ab-C study design has been reviewed by the Research Ethics Board of Unity Health Toronto (St. Michael's Hospital). As part of the ethics process, any changes to the Ab-C are reviewed annually.

Data and Sample Access

Who has access to my data and samples?

Ab-C staff: A limited number of Ab-C staff and partner laboratories have access to your data and samples for purposes of developing the database and doing quality control tests. A more limited number of staff have access to your identifying information for purposes of contacting you in the future, for updating your information, for linking with other provincial health databases (if consent was provided), or for registering a withdrawal. Your identifying information will not be released to a non-research related third party without your consent or unless it is required by a valid court order or by law.

Researchers: Researchers in public institutions in Canada and other countries can request access to de-identified study data (but not your personal information, such as your name or address) to conduct specific research projects. Approval is granted by the Ab-C Scientific Committee and must also be approved by a Research Ethics Board. Approved researchers must sign confidentiality and data access agreements, which bind all users to the terms and conditions, set out by the Ab-C. Researchers from private businesses will not have direct access to your data and samples, but may be part of a research team.

You can always request access to your information.

Your information will not be given to non-research related third parties. In the very unlikely event that we are required by law to provide your information to a third party, we would inform you first.

Data sharing with CITF (COVID-19 Immunity Task Force)

De-identified data from this study will also be shared with CITF. The CITF is a national initiative funded by the Government of Canada to perform research related to COVID-19 immunization. The CITF will collect data to share with researchers in Canada and internationally so as to understand the science underlying COVID-19 immunity, COVID-19 infection rates in the Canadian population, and to study related health outcomes.

No directly identifying information will be provided to the CITF, nor included in the CITF Database.

The CITF will share your de-identified data with researchers in Canada and internationally. Your de-identified data will be shared with researchers performing for-profit research and non-profit research. The data will be used to perform research concerning COVID-19 and related health outcomes. Your data may be used alone or in combination with other data, including other health data. Data that has either been anonymized (i.e. you cannot be identified), or aggregated (i.e. is accumulated with the data of others), may be made open to the public using a website that anyone can access. Your data may also be shared with other COVID-19 research databases that follow similar protections and procedures as the CITF Database.

The data on the CITF Database will be stored indefinitely, or, until it is no longer useful for research, or, an ethics committee decides otherwise. If you withdraw your consent to participate in this research, we will contact the CITF, which will remove your data from the CITF Database. If some of the data have been shared with other researchers or published, it may not be possible to remove this part of the data.

Access to provincial health databases and other health information

How will Ab-C access my information contained in provincial health databases?

If you have given us your provincial health card number and have authorized the study to access provincial health databases, the Ab-C team will have an agreement with the respective organization. The terms and conditions of access to these provincial databases will

depend on each province, the provincial laws and the agreement with Ab-C.

Safeguarding participant confidentiality

Who abides by this policy?

a) All entities forming part of the overall governance structure of the Ab-C;
b) The principal investigators, co-investigators, institutions and all staff responsible for collecting data and/or samples for inclusion into the Ab-C research platform;
c) All researchers seeking access to Ab-C data for specific research projects, and as approved by relevant research ethics boards and the Ab-C Scientific Committee. These individuals are held accountable for compliance either directly (e.g. through terms and conditions in data sharing agreements, user agreements, and confidentiality agreements).

Email Communication
You will get an email with an attachment containing your individual results.

You should be aware of the risks of using email to communicate:

- Information travels electronically and is not secure in the way a phone call or regular mail would be.
- If someone sees these emails, they may know that you are a participant in this study or see the health information included in the email and/or text.
- Emails may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, "free internet" providers).
- Copies of an email may continue to exist, even after efforts to delete the email and/or text have been made.
- There is always a chance with any unencrypted email however remote, that it could be intercepted or manipulated.

Changes to the Ab-C Privacy Policy
The Ab-C Privacy Policy may be updated occasionally to reflect the feedback of Ab-C participants and stakeholders. If you have any questions or comments about your privacy and confidentiality within Ab-C, you can contact us:

Toll-free: 1 833-837-8222 or 1-833-TEST-ABC

Email: AbCstudy@UnityHealth.to

By mail:
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Future contact for research purposes
We would also like to ask that you consider providing consent to be contacted about future research studies. The information that you should consider before agreeing to this is outlined below, and you can choose to opt in on the online consent form.

The Principal Investigator's study team may contact you by email or telephone for health-related research done in the next 5 years. If you opt in, all information collected for the Ab-C Study will be stored for future contact for research. This information will be stored and accessed in accordance with the Ab-C Privacy Policy described above.

You are not obligated to participate in any research studies that you are contacted about. If you no longer want to be contacted about future research studies, please contact the study coordinator at 1-833-837-822 (1-833-TEST-ABC) or abcstudy@unityhealth.to.

QUESTIONS:
If you have any questions, you can contact the study coordinator at 1-833-837-8222 or 1-833-TEST-ABC or abcstudy@unityhealth.to about any side effects or study-related injuries that you experience.

If you have questions about your rights as a research participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact the Unity Health Toronto Research Ethics Board Office at 416-864-6060 ext. 42557 during business hours (9:00am to 5:00pm Eastern Time).
Unity Health Toronto is a health network that includes Providence Healthcare, St. Joseph's Health Centre, and St. Michael's Hospital.