Participant Information and Informed Consent Form

An Approach to Screening for COVID-19 at YVR

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When we say "you" or "your" in this consent form, we mean the research participant; "we" means the Principal Investigator, Co-Investigator, and other research staff.

Invitation:

You are invited to take part in a voluntary research study conducted by **The University of British Columbia and Providence Health Care,** sponsored by **WestJet, KLM and Vancouver Airport Authority**. The experimental study investigates point-of-care rapid test device for detecting COVID-19. The study will help inform the safest and most efficient way of testing departing passengers prior to security screening at Vancouver International Airport (YVR). "Experimental" means that the testing system is currently under investigation. This study is also evaluating a new passenger management system.

This information sheet and consent form provides you with essential information about this study and your rights as a study subject, so that you can make an informed decision about your participation. If you have questions that are not properly explained or answered in this informed consent form, someone from the study staff will be available to provide more information.

In this information sheet and consent form, a reference to "**Airline**" means either WestJet or KLM, as applicable, based on which of these two airlines you have a scheduled flight with.

Background and purpose of the study:

Currently, airlines require travellers to wear masks and physically distance themselves while traveling. However, the majority of public is still worried about the potential increased risk of contracting COVID-19 during air travel, especially during long flights.

Objective:

The primary objective of this pilot study is to determine the feasibility and effectiveness of a COVID-19 screening program for passengers departing from YVR.

Research Study:

We are inviting all travellers meeting the Inclusion/Exclusion Criteria below to participate in this important research study. Following informed consent, we will collect nasopharyngeal (NP) swab sample and oral rinse sample before your time of departure. (*A nasopharyngeal swab is a method for collecting a clinical test sample of nasal secretions from the back of the nose and throat. The sample is then analyzed for the presence of organisms or other clinical markers for disease.*) The collected NP swab sample and oral rinse sample will be tested using two separate point-of-care rapid test devices on site. The remaining NP swab and oral rinse samples will be transferred back to the research lab at St. Paul's Hospital for additional testing. If both point-of-care rapid tests come back "negative", you will be allowed to continue with your scheduled flight. If either rapid test comes back "positive", you will be denied boarding and asked to reschedule the flight – for the safety of all staff and passengers. In addition, a new NP swab will be obtained and sent to an accredited provincial clinical lab at St. Paul's Hospital for confirmatory diagnostic testing. More details regarding "positive" results are available from the Study Team.

Who can participate in this study?

You may be able to participate in this study if:

1. You have access to accommodation in Canada for safe-isolation as per public health guidelines.
2. You are between the ages of 13 – 90.
3. You are travelling on any Airline flight.
4. You have a minimum of 70 minutes (if travelling within Canada) or 90 minutes (if travelling International) of free time prior to the scheduled flight's departure.

Who should not participate in this study?

You will not be eligible to participate in this study if:

1. You have previously tested positive for COVID-19 within the past 90 days.
2. You do not provide written informed consent by signing and returning this Informed Consent Form.

What does the study involve?

Screening Test:

- Screening Test for COVID-19 is intended to identify occurrence at the individual level even if there is no reason to suspect infection—e.g., there is no known exposure. This includes, but is not limited to, screening of non-symptomatic individuals without known exposure with the intent of making decisions based on the test results. Screening Tests are intended to identify infected individuals without, or prior to development of, symptoms who may be contagious so that measures can be taken to prevent further transmission.
- Health Canada-approved Panbio Covid-19 Ag Rapid Test Device by Abbott Rapid Diagnostics (approved for Lab-based test and Point of care test on 2020-10-05) will be used in this study. The collected NP swab sample and oral rinse sample will be tested using two separate point-of-care rapid test devices on site. The remaining samples will be transferred back to the research lab at St. Paul's Hospital for additional testing.

Diagnostic Test:

- Diagnostic Test for COVID-19 is intended to identify occurrence at the individual level and is performed when there is a reason to suspect that an individual may be infected, such as having symptoms, positive result from screening test, suspected recent exposure, or to determine resolution of infection.
- If your screening result is "positive", you will be denied boarding and asked to reschedule the flight – for the safety of all staff and passengers. A new NP swab will be collected and sent to an accredited provincial clinical lab at St. Paul's Hospital for confirmatory diagnostic testing.

Note: the Screening Test result does not medically diagnose COVID-19 infection. A positive Screening Test result needs to be further confirmed by Diagnostic Test using gold standard diagnostic testing. Similarly, a negative Screening Test result does not medically diagnose an absence of COVID-19 infection.

What Happens if I Consent to Participate:

Should you choose to consent to the study the study coordinator will then ask that you provide nasopharyngeal (NP) swab sample and oral rinse sample.

NP swab: the study coordinator will move to your side and apply the Swab through your nasal cavity to the back of your nasopharynx – the area directly above the back of your throat – to get the best test sample.

Oral Rinse: You will be offered saline, but do not swallow the solution. Close your mouth, and swish the saline with your tongue and cheeks gently inside your mouth. After about 15-20 seconds, gently spit the saline into the specimen container.

The collected NP swab sample and oral rinse sample will be tested using two separate point-of-care rapid test devices on site. The remaining NP swab and oral rinse samples will be transferred back to the research lab at St. Paul's Hospital for additional testing (e.g., validation of point-of-care rapid tests).

After you have provided the samples, you will be guided out of the testing area and back into the airport terminal. You will be provided with a questionnaire to complete while you wait for your screening test results. The questionnaire will ask you for basic overall medical history (e.g., demographics, vaccination history, lung/heart disease history, current smoking status, and current symptoms).

What Happens When my Screening Results are Ready?:

In approximately 20 mins the study coordinator will invite you into a private Results Office inside the airport to give you the results of the screening test. If you would like a copy of your consent form, you can request it from the study coordinator.

If your screening test is Negative for COVID-19, the Airline staff will be notified that you are cleared to fly. The Respiratory Therapist will provide you with a small info sheet about your negative screening test.

If your screening test is Positive for COVID-19 (either NP swab sample or oral rinse sample), you will also be asked to provide a second NP Swab which will be used to conduct the confirmatory diagnostic test at an accredited provincial clinical lab. The Airline staff will be notified of your status and you will be denied boarding on your scheduled flight. The Airline team will recover all of your checked baggage and provide you with options to allow your safe travel back home. The Respiratory Therapist will provide you with a small info sheet about your positive screening test (including Airline flight rebooking options) and provide you with a copy of the Provincial COVID-19 Quarantine Guidelines.

What Happens When my Confirmatory Diagnostic Test is Ready?:

Following your positive screening test, if the confirmatory diagnostic test at the accredited clinical lab is **Negative** for COVID-19, you will be contacted by our research team who will inform you of your updated status. We will also inform the Airline staff who will update your travel profile allowing you to rebook you flight. The Airline will rebook you and/or your Travel Companions on the next available comparable flight, up to a maximum of 14 days from the date of your original departure ("Rebooking Window 1").

Following your positive screening test, if your confirmatory diagnostic test is **Positive** for COVID-19, you will be contacted by our research team who will inform you of your confirmed status. Our team will also contact the Airline staff who will update your travel profile restricting your travel abilities until after you have completed your 14 days of quarantine. The Airline will rebook you and/or your Travel Companions between 14 days after your original departure date up to 30 days after your original departure date (the "Rebooking Window 2"). Our Research Team will also inform Vancouver Coastal Health or the relevant a public health authority of your positive Diagnostic Test (RT-PCR diagnostic test) results, in order to initiate contact tracing measures.

If you prefer to cancel your flight regardless of the results of your confirmatory diagnostic test, or if there is no comparable rebooking options within Rebooking Window 1 or Rebooking Window 2, as applicable, the Airline will refund the unused portion of your ticket and/or the unused portion applicable to your Travel Companions, as Airline travel credit; an Airline representative can assist with providing more detailed information about rebooking flights.

Please see Disclaimer at the end of the document under Appendix (a)

What will happen to my biological samples?

- The collected NP swab sample and oral rinse sample will be tested using two separate point-of-care rapid test devices on site. The remaining samples will be transferred back to the research lab at St. Paul's Hospital for additional testing.
- If the screening result is "positive" (either NP swab sample or oral rinse sample), you will be denied boarding and asked to reschedule the flight – for the safety of all staff and passengers. In addition, a new NP swab will be obtained and sent to an accredited provincial clinical lab at St. Paul's Hospital for confirmatory diagnostic testing.
- **Future Use**: The study team will store the collected samples for 10 years. After this period, the samples will be destroyed. We will conduct additional COVID-19 testing, as well as other research related to COVID-19 (and related conditions). The samples will be kept at UBC Centre for Heart Lung Innovation in -80 degrees C freezers. No data/samples will be transferred outside of Canada. All samples will be anonymized (no link remaining to PHN or other identifier).
- **Governance**: We will have a steering committee comprised of the investigators, study sponsors, and representatives from Vancouver Coastal Health, and Ministry of Health who will provide oversight of all materials and data collected for this project. The Steering Committee will meet on a monthly basis to review all data and make strategic decisions regarding the study. The Steering Committee will be chaired by the PI and Project Manager.

What are the possible harms and discomforts?

- The Nasopharyngeal Swab is a little uncomfortable during sample collection, but our Study Coordinators are trained to make the experience as comfortable as possible.

What are the potential benefits of participating?

- There may or may not be direct benefit for you in taking part in this study, aside from contributing to the learnings around the benefits of rapid COVID-19 Screening tests in the air travel context.
- For **WestJet passengers only**, a passenger who completes the research study will receive a 20% discount on their next WestJet flight (restrictions apply).

Your participation is voluntary:

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. **However, if you elect to withdraw from the study at any time after you have screened positive for COVID-19 in this study, the Airline is required by applicable law to deny you, and will deny you, boarding on your scheduled flight.**

You should be aware that there is a difference between being a patient and being a research participant (which we also refer to as a study subject). As a patient all medical procedures are carried out for your benefit only according to accepted standard practice. As a research participant in a study such as this, you must also take into account the requirements for the research study. These may include procedures that are not part of standard practice or are not yet proven. This consent form describes the screening and diagnostic tests that are being carried out for research purposes in this study. Please review the consent document carefully when deciding whether or not you wish to be part of this research study and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form. Except as described in this consent or unless required by law, no information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent. However, due to public health concerns with the spread of COVID-19, if you screen positive for COVID-19 using the point-of-care rapid test device used in this study, your identity will be disclosed to:

- Accredited clinical lab led by Dr. Marc Romney at St. Paul's Hospital for confirmatory diagnostic testing;
- Vancouver Coastal Health or the relevant public health authority - notified upon confirmation of positive confirmatory testing result; and
- Both Vancouver Airport Authority and the Airline (WestJet or KLM, as applicable based on your travel plans) and their representatives because, as described further below, you will be denied boarding on your scheduled flight departing from YVR (only your name, screen result, and confirmatory test result will be shared).

Who is conducting this study?

This study is being conducted by The University of British Columbia (UBC) and Providence Health Care, and is funded by Vancouver Airport Authority and WestJet. The amount of the financial compensation to researchers for conducting the research is associated with obligations defined in a signed contractual agreement between UBC and sponsors. Researchers must serve the interests of the participant and also abide by their contractual obligations. For some, the payment of financial compensation to the researchers can raise the possibility of a conflict of interest. You are entitled to request any details concerning this compensation from the Study Team.

What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information collected from you up to the point of your withdrawal (including, where applicable, information obtained from your biological samples) will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected. In addition, if you elect to withdraw from the study at any time after you have tested positive for COVID-19 in this study, the Airline is required by applicable law to deny you, and will deny you, boarding on your scheduled flight.

If samples have been collected before you withdraw, they will be destroyed or returned to the facility from which they were obtained. There may be exceptions where the samples will not be able to be withdrawn for example where the sample is no longer identifiable (meaning it cannot be linked in any way back to your identity).

Can I be asked to leave the study?

The study may also be stopped at any time by the sponsor or the Research Ethics Board or Health Canada if new information arises about the safety of the study test kits. The reasons for study stoppage will be explained to you by the study team.

How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, as described above, research records and health or other source records identifying you may be disclosed to **WestJet, KLM, Vancouver Airport Authority,** Vancouver Coastal Health or the relevant a public health authority, Health Canada, and University of British Columbia Providence Health Care Research Ethics Board for the purpose of monitoring the research study. Except as described in this Informed Consent Form, no information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the

information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study team.

Your personal information will be used for only as long is needed for the study and further research, with your consent. It may be retained for longer, where required by law. St. Paul's must retain data from clinical studies for a minimum of 25 years.

Reportable Diseases

Your personal information or information that could identify you will not be revealed without your express consent unless required by law. If facts become known to the researchers which must be reported by law to public health authorities or legal authorities, then your personal information will be provided to the appropriate agency or authority: Positive COVID-19 test.

What will the study cost me?

All research-related medical tests that you will receive during your participation in this study will be provided at no cost to you. Any other medical care or treatment that you require, including as a result of a diagnosis with COVID-19 are your responsibility under your British Columbia provincial medical care plan and/or any private insurance that you maintain.

I understand that if I test positive for COVID-19 in this study, the Airline is required by applicable law to deny me, and will deny me, boarding on my scheduled flight departing from Vancouver International Airport and that the only compensation that will be offered to me as a result is to reschedule my flight or to cancel and receive Airline travel credit for that flight as set out and subject to the restrictions described under the heading "What does the study involve" in the Informed Consent Form.

Will I be paid for being in the study?

No, you will not be paid for your participation in this study. However, if you are a WestJet passenger participating in the study, upon completion of the research study, you will receive a 20% discount code on your next WestJet flight as described above.

Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the primary Respiratory Therapist Lynda Lazosky at 778-389-9074.

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this trial, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number H20-03225 when you call.

An Approach to Screening for COVID-19 at YVR

Study Participant Consent Statement

By giving consent orally or by signing *this* form, I agree:

- I have read and understood the information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had been able to ask questions and have had satisfactory responses to my questions.
- I understand that except as described in the Informed Consent Form, all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from the study at any time, and this will not change the quality of care that I receive.
- I understand that, except as set out in the Informed Consent Form, I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I understand that if I test positive for COVID-19 in this study, the Airline is required by applicable law to deny me, and will deny me, boarding on my scheduled flight departing from Vancouver International Airport and that the only compensation that will be offered to me as a result is to reschedule my flight or to cancel and receive Airline travel credit for that flight as set out and subject to the restrictions described under the heading “What does the study involve” in the Informed Consent Form.
- I have read this form and I freely consent to participate in this study.
- I will receive a signed and dated copy of this consent form for my own records.
- I consent to participate in this study.
- I understand that two types of samples will be collected: nasopharyngeal Swab sample and oral rinse sample

Complete the appropriate signatory below:

Study Participant:

I know that, except as set out in the Informed Consent Form, I can withdraw this consent for use of my medical and personal information at any time.

_____	_____	_____
Participant's Signature	Printed Name	Date

Person Conducting Consent (STAFF CONFIRMATION)	
Signature:	Date:
Print Name:	Role:

Parent/Guardian and/or Substitute Decision Maker Consent:

This consent form was read by the parent(s)/guardian(s)/substitute decision-maker (legally authorized representative), and both the person reading this consent form and the investigator are satisfied that:

- The study information was accurately explained to, and apparently understood by, the child/participant.
- The child/participant was given an opportunity to ask questions, and all questions have been answered.
- The child/participant assents to participating in the research.

_____

Participant Name

_____ _____ _____

Parent/Representative's Signature Printed Name Date

Person Conducting Consent (STAFF CONFIRMATION)	
Signature:	Date:
Print Name:	Role:

Appendix

Appendix (a):

- **Except for the rebooking assistance or Airline travel credit described above being provided by the Airline to study participants who test positive in this study for COVID-19, your participation in this study does not entitle you or your Travel Companions to be reimbursed or otherwise compensated for any costs or other amounts incurred by you or your Travel Companions as a part of your participation in this study or testing positive for COVID-19, including but not limited to lost wages, lost or additional travel costs (such as lost hotel, accommodation or excursion fees from cancellations or having to incur extra nights in a hotel or other accommodation, lost car rental costs, any costs incurred to any airline other than the Airline or any connecting or subsequent flights, lost wages or other amounts) , even if it is later determined that the experimental test conducted in this study was incorrect (was a false positive) and you did not actually have COVID-19.**