PARTICIPANT INFORMATION PAGE

Voluntary Asymptomatic Saliva COVID-19 Detection and Variant Tracking at the University of Waterloo (ASTRAW)

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Introduction:
You are being invited to participate in a COVID-19 research project lead by Professor Trevor Charles and Professor Jozef Nissimov of the Department of Biology at the University of Waterloo. The purpose of this project is to assess the feasibility of using frequent saliva-based screening to detect asymptomatic COVID-19 infection.

To help you make an informed decision regarding your participation, this letter will explain what the study is about, the possible risks and benefits, and your rights as a research participant. If you do not understand something in the letter, please ask one of the study coordinators prior to consenting to the study, by emailing your questions to saliva.testing@uwaterloo.ca.

This study is funded with a grant from the UW Strategic COVID-19 Research Award.

Why is this research being done?

At least 1 in 3 COVID-19 cases are asymptomatic, so the detection of asymptomatic infections can effectively contribute for controlling the virus dissemination. The main goals of the project will be to use rapid in-house testing of individuals on campus for the detection of asymptomatic infections, thereby contributing to the prevention of outbreaks at the University of Waterloo. Saliva-based testing has large advantages over the clinical standard, deep nasal swab testing, including but not limited to ease of administration, cost per test, and safety of medical personnel. We aim to develop and implement high-capacity testing procedures that are saliva-based to enable large-scale and routine testing of asymptomatic individuals at the University of Waterloo to better identify cases, isolate the infected and limit the spread of COVID-19. We think that most people would choose to get tested more often if the test was easier and that workplaces would be safer if we could catch infections early.

What is the purpose of this study?

With this study we aim to assess the success, impact, and practicality of saliva-based COVID-19 testing for scale up to include testing for large asymptomatic populations in a university laboratory setting. In addition to prevention of community, workplace, and school spread and infection of COVID-19, we believe the impact of saliva-based routine testing on factors such as quality of life in the training/workplace environment will be substantially improved.

What does participation involve?
If you choose to participate in this research study, we will ask you to provide 1 mL (less than a teaspoon) of your saliva, 2- times a week by spitting/drooling in a tube. Family members of the participants with age of 18 or older will be able to participate on the research upon a separate (individual) registration and consent.

To participate, you will be required to refrain from eating and drinking anything other than water for at least 1 hour prior to providing your sample. In addition, we ask that you check your email at least once a day for important information regarding the study and/or results of your test. The test we are performing is not yet licensed or approved by the province of Ontario or Health Canada and therefore if you receive a potential positive test result, you should 1) Confirm your results at a certified Ontario provincial COVID-19 testing center, 2) Self-isolate until your result is verified by a provincial COVID-19 test conducted by the province of Ontario and 3) We invite you to share your test certified test result with us to help us improve our diagnostic test.

We do not yet know how sensitive this test is and whether it is as good or better than the conventional nasopharyngeal swab and laboratory test performed at an approved provincial testing site. Thus, participation in this study is not a substitution for monitoring your health, staying home from work and getting tested at a provincial testing site if you are experiencing any signs or symptoms of COVID-19. If on any day during the course of the study you are experiencing signs or symptoms of COVID-19, you should NOT submit a saliva sample until at least 14 days have passed since symptoms first appeared OR you have received a negative test result from a licensed provincial testing facility and are no longer experiencing symptoms of COVID-19 infection.

To ensure anonymity, participants will be identified with barcodes. Each participant will be provided with a 5-week sampling kit including 10 barcoded labels, 10 sterile tubes, 10 Ziplock bags, and an instruction sheet. At the end of 5 weeks the participant can request the next sampling kit by email (saliva.testing.uwaterloo.ca). Kits will be given to registered participants on Mondays and Wednesdays, between 9 am and 12 pm (dropbox location: Biology 1), or upon arrangement by email (saliva.testing@uwaterloo.ca) for picking up their kits at the same location, but on alternative date/ time. Participants must register their barcodes online immediately after receiving their sample kits. A workflow sheet containing QR to rapid access to barcode registration is provided on the kit.

We will also ask you to fill out a questionnaire at the beginning and end of the study to assess your work habits and opinions on workplace safety during the COVID-19 pandemic.

What tests will be done on the saliva sample that I provide?

Each saliva sample you provide will be tested for SARS-CoV-2 viral particles. Negative samples will be destroyed in 24-48h after collection. With your permission, positive samples will be anonymized and kept for further virus genomic analysis. Under no circumstances will your own DNA be analyzed. It will not be possible to withdraw positive samples after they been anonymized.

When and how can I receive my results?

You will receive an email from the study coordinator ONLY if your saliva sample Is found to contain COVID-19 viral particles within two days of providing your sample. You will receive a follow up phone call to the email within 12 hours of receiving the email. If you sample is negative for COVID-19 viral particles you will not receive an email or a phone call. Both negative and positive results in this study, should be treated as potential negatives and potential positives, respectively. Results from this study are not "official" results, and if you are feeling signs or symptoms of COVID-19 infection you should visit and get tested at an approved provincial testing site regardless of the results you received from this study.

What are the possible risks and discomforts?

1) Saliva collection is painless. Receiving a positive test result may cause you stress, until the results confirmed by a provincial testing site. A positive test result from this study means that you should not attend work or social events until you have the results confirmed by the province of Ontario. Although this may inconvenience you, it is essential to protect the people you encounter.

2) Loss of Confidentiality: We will keep your information confidential by giving your samples a study number instead of using your name. Your email will be used to log in and answer to online surveys, but your email will not be linked to your name. It is possible that people may be able to identify you by your email address.

How many people will be in this study?

We will recruit approximately 1000 people.

What are the possible benefits for me and/or society?

We cannot promise any personal benefits; however, we hope that rapid and frequent testing may help reduce the spread of COVID-19 and allow us to get back to work more safely.

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. This study is strictly for research purposes and choosing not to participate will not affect your health care, employment, or treatment in any way.

What are my alternatives to participation?

You may choose not to participate in the study. If you are a University of Waterloo s employee, your participation will not affect the conditions of your employment or promotion.

Please take as much time as you need to consider your participation in this study. You are welcome to ask any questions about this research program, now or in the future.

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 email, gender, age, and phone number will be removed from the data and will be replaced with a barcode number. A list linking the barcode number with your contact information will be kept in a secure place on a password protected computer and separate from the lab results. Only the research team will have access to study data.

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.

Can participation in this study end early?

If you volunteer to be in this study, you may withdraw at any time, and this will in no way affect the quality of care you receive or employment at this institution. Once you withdraw, you will receive an email confirming you withdrew and inviting you to participate of the end-of-research survey (optional). You may also refuse to answer any questions you don't want to answer and 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?

No. You will not receive any compensation for donating saliva to this research program.

Will there be any costs?

No. Your participation in this research study will not involve any costs to you or your health care insurer.

If I have any questions or problems, whom can I call?

Contact information of the researcher

If you have any questions about the research now or later, or if you think you have a research-related injury, please contact the study coordinator Dr. Patricia Dörr de Quadros at **519-888-4567 x40570** or by email at saliva.testing@uwaterloo.ca

Contact Information of Research Ethics Board

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB 43239). If you have questions for the Board contact the Office of Research Ethics at 1-519-888-4567 ext. 36005 or reb@uwaterloo.ca.