St. Michael's

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Informed Consent Form for Participation in a Research Study

Study Title:	COVID-19 Ring-based Prevention trial with Lopinavir/ritonavir (CORIPREV LR)
Sponsor's Study ID:	CORIPREV-1
Sponsor-Investigator:	Dr. Darrell Tan St. Michael's Hospital, Division of Infectious Diseases Positive Care Clinic 30 Bond Street, 4-179 Cardinal Carter North Wing Toronto, Ontario, Canada M5B 1W8 (416) 864-5568
Co-Principal Investigators:	Dr. Allison McGeer Dr. Adrienne Chan
Site Study Doctor:	Dr. Darrell Tan
Study Project Manager:	Attia Qamar 416-864-6060 x 77325 Attia.Qamar@unityhealth.to
Study Site Coordinator:	Alexandre Schnubb 416-864-6060 x 77105 Alexandre.Schnubb@UnityHealth.to
Sponsor/Funder(s):	Canadian Institutes of Health Research St. Michael`s Hospital Foundation AbbVie
Emergency Contact Number: (24 hours / 7 days a week)	416-685-9636

Non-Emergency contact numbers are noted at the end of this document under the section heading "Contacts".

:

INTRODUCTION

You are being asked to consider participating in a clinical trial (a type of research study) because in the past week you have been in close contact with someone who has or may have COVID-19, and because you agreed to be contacted for this trial. You will be eligible to participate only if that close contact is confirmed to have COVID-19 on laboratory testing.

This consent form provides you with information to help you make an informed choice. Please read it carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this study. This consent form is for adult study participants. Participants under the age of consent will also be given an assent form about the study.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

Written consent must be obtained before any study procedure can be done. This means you should not perform any study related tasks or take any study drugs until you have read and signed this consent form. Since you will have to isolate yourself because of being in close contact with someone who has COVID-19, you may provide written consent by fax, email, picture messaging or video (study staff witness you signing the consent over video-link). The original paper signed consent will be collected in-person at your first in-person study visit. You will be offered a copy of the signed informed consent form, signed by you and the study staff member who obtained your consent, by fax, e-mail or regular mail.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study. The sponsoring institution for this study is St. Michael's Hospital and the sponsor-investigator is Dr. Darrell Tan. Dr. Tan is receiving funding for study operations from the St. Michael's Hospital Foundation and the Canadian Institute for Health Research (CIHR) and is receiving in kind-support in the form of cost-free study drug supply from Abbvie pharmaceuticals.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses cause infections in the respiratory system. This is the system in our body responsible for breathing. These infections can range from the common cold to more severe diseases. COVID-19 is the disease caused by the most recently discovered coronavirus. COVID-19 can be spread from person to person even if the infected person does not have any symptoms. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. Despite ongoing efforts to prevent spread, COVID-19 has rapidly spread to most of the world.

There are many symptoms of COVID-19 including mild cold-like symptoms to more extreme ones like pneumonia (infection of the lungs). Pneumonia can cause a cough with phlegm, fever, chills, and difficulty breathing. In some cases, it can be life threatening. The incubation period, the period between exposure and start of symptoms, is thought to be up to 14 days.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see whether taking a medication called lopinavir/ritonavir (also known by the brand name Kaletra®) by mouth for 14 days can prevent COVID-19 infection in people who have been in contact with someone who already has COVID-19. Taking medication to prevent infection in this way is called post-exposure prophylaxis (PEP). Kaletra® is not approved for use as COVID-19 PEP. Health Canada, the regulatory body that oversees the use of natural health products/drugs/devices in Canada, has no objection to its investigational use in this study. This study will be the first time Kaletra® is being studied for use as COVID-19 PEP.

This study will include people who have recently been in contact with someone who already has COVID-19. Half of the participants will get Kaletra® for 14 days and the other half will not. Participants will be tested for COVID-19 up to 4 times during their first 2 weeks in the study. These test results will be compared between participants who took Kaletra® and those who did not, to determine whether Kaletra® works as PEP. Final results of the study should be known approximately 3 months after the study is finished.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to get tested for COVID-19 or to receive health care. At this time, there are no approved treatments for COVID-19 and no approved medications for preventing COVID-19 infection after exposure. Current methods of prevention include isolating from the public or keeping a distance of at least 2 meters between yourself and other people. **If you agree to participate in this study, you may not be able to enroll in other COVID-19 prevention studies.**

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 1220 people will take part in this study in Toronto and Vancouver. Enrollment will begin in April 2020 and continue until the target number of people are enrolled or until December 31st, 2021. Study sites in Toronto will include Toronto General Hospital, St. Michael's Hospital and Sunnybrook Hospital. Vancouver will have one site at St. Paul's Hospital.

WHAT WILL HAPPEN DURING THIS STUDY?

If at any time you feel ill or feel you are in need of medical care, immediately contact your health care provider or go to the Emergency Room of your nearest hospital. In case of emergencies call 911.

Assignment to a group

If you decide to participate then you will be "randomized" into one of two study groups, also called arms. There are two arms in this study: the 'active arm' that will get Kaletra® and the 'control arm' that will not. Randomization means that you are put into a study arm by chance (like flipping a coin). There is no way to predict which arm you will be assigned to. You will have an equal chance of being placed in either arm. Neither you, the study staff, nor the study doctors can choose what arm you will be in. You will be told which arm you are in.

In this study, all the people who were exposed to the same COVID-19 positive person (also called the index case) will be randomized to the same study arm. This group of individuals will be called a ring. Randomization will not happen until all the members of the ring have told the study team verbally whether or not they want to participate, or until 24 hours have gone by since the study team first learns that the index case has confirmed COVID-19 infection.

It is possible that you may be invited to consider participating in this study more than once, if

you have been exposed to more than one index case. If you are already enrolled in this study but have been assigned to the 'control arm', and then are invited to participate again because you are part of a second ring, you may leave the first ring and be randomized according to the second ring if you wish. If during or after the study you have another exposure, you can re-enroll, as long as you will not have taken Kaletra® within 2 days of being randomized.

WHAT IS THE STUDY INTERVENTION?

Lopinavir/ritonavir (Kaletra®) is a medication that has been used in combination with other medications for both the treatment and prevention (PEP) of human immunodeficiency virus (HIV), the virus that causes AIDS. Lab and animal tests suggest that Kaletra® might work against COVID-19. If you are randomized to receive the study drug, you will be asked to take two Kaletra® tablets, two times a day, for 14 days. Children may be given Kaletra® in liquid form and the dose will be based on weight. You will be provided with a handout on how to store and handle the form (liquid or tablet) of Kaletra® you are given.

Safety Information and Side Effects:

Safety information on Kaletra® is based on its use in HIV-positive people, in combination with other drugs used to manage HIV. Kaletra® has being used for HIV for over 20 years and is considered to be a safe drug. Most of the side effects experienced with Kaletra® involve stomach upset, such as diarrhea, nausea and abdominal (stomach and gut) pain. Study staff may provide you with dimenhydrinate (Gravol) to help with nausea and loperamide (Immodium) to help with diarrhea.

There is a risk for more severe side effects if the drug is taken for more than 28 days. In this study, Kaletra® will be taken for 14 days. Some people find that the Kaletra® liquid does not taste good.

Kaletra® cannot be taken if you have an allergy to it or if you are breastfeeding. It may be taken in tablet form during pregnancy. The liquid form of Kaletra® has a high enough alcohol content that it should not be taken by pregnant women or those with kidney issues.

Kaletra® can interact with some medications in ways that may cause either the other drug or Kaletra® to become ineffective. There is a list of medications that you cannot take while you are taking Kaletra®. The study team will ask you about the medications you are taking to make sure you are able to participate in the study.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

When Kaletra® is taken by a person living with HIV, it needs to be combined with other anti-HIV medications. Unless you have previously been diagnosed with HIV, then in order to participate in this study, you will need to be tested for HIV. If you test positive for HIV you will be referred to an HIV specialist right away, but you can still participate in this study.

WHAT ARE THE STUDY PROCEDURES?

Participation in the study will span 90 days. The table below indicates the study visits and the procedures that will be conducted during each visit. Because you have been exposed to someone diagnosed with COVID-19, you will need to isolate yourself from other people for 14 days after the exposure. For this reason, and to protect study staff, every effort will be made to conduct the Day 1, Day 7 and Day 14 visits remotely via telephone or video-link. In some cases, for example, for participants in a retirement home, study staff may use personal protective equipment while carrying out the visits in-person.

Study Visits	**Screening (Day 1)**	**Enrollment (Day 1)**	**Day 7**	**Day 14**	**Day 35**	**Day 90**
Study Procedures	**Remote Visit**	**Remote Visit**	**Remote Visit**	**Remote Visit**	**In person Visit**	**Remote Visit**
Eligibility & Informed consent	X					
Randomization & Enrollment	X					
Kit Delivery (including Study Drug Kaletra® for Active Arm)		X				
Interview by study staff		X	X	X	X	X
Adherence diary (for Active arm)		Daily on days 1-14				
Symptom diary		Daily on days 1-14, then on days 21, 28 and 35				
Questionnaires		X	X	X	X	X
HIV self-test (for Active Arm)		X				
Dried blood spot*		X		X		
Self-collected nasal swab**		X	X	X		
Blood for COVID-19 testing		X***			X	
Stored blood specimens					X	

*Only for the active arm on day 1 to test for COVID-19, and for a randomly selected group of active arm participants on day 14 to test for study drug levels
Other types of respiratory specimens may be collected depending on availability of supplies
** Two swabs may be collected at day 14. If you begin to feel symptoms of becoming ill such as cough, fever, etc. you can do a 3rd self-swab during the first 13 days of the study and only one swab will be done at day 14.
***Blood for COVID-19 testing will only be collected at day 1 if the study participant is recruited at a hospital or long-term care facility. Self-isolated participants will have blood drawn at the in-person visit on day 35.

Informed Consent:

The purpose of informed consent is to provide you with all of the information you need to make an informed choice about your participation in the study. The process of informed consent is described in the 'Introduction' section of this consent form. The informed consent process is continuous and involves the discussions you have with study staff during the course of the study, in addition to the written consent form itself. If changes to the study are made that require changes to the consent form, you will be informed and asked to sign the most recent version. Study staff are always ready to answer any questions you may have.

Contact Information

Upon providing consent you will also be asked for multiple forms of contact information to contact you directly. This may include e-mail, home phone, cellular phone, fax. You will also be asked to provide contact information for two back-up contacts, including full names, addresses, telephone numbers and email addresses. The reason for collecting all this contact information is that we must have sufficient information to contact you quickly and/or learn about your health status in case you do test positive and/or experience a more serious COVID-19 illness.

Study Kit Delivery:

If you agree to participate, you will be asked to provide your complete mailing address for delivery of study materials. A kit will be delivered to you containing all of the study supplies you will need for study participation during the first 13 days. Kits for both study arms will include: 4 swab kits, a thermometer, material for packaging swab samples for return to the lab for testing, specimen labels and printed instructions. You will also receive paper versions of the adherence and symptom diaries if you are unable to complete these over the internet. If you are in the active arm you will also get study drug, an HIV self-test kit and materials to collect the dried blood spots.

Interviews

At the Day 1 visit, study staff will conduct an interview to determine:

- Contact information
- Information about your exposure to the COVID-19 index-case: relationship, timing/ intensity/ frequency of contact, any protective measures you may have taken during the contact
- Medical history: medications and herbal products and supplements you are taking, medical conditions, smoking status and your current symptoms

At each of the follow-up visits (Days 7, 14, 35, 90) study staff will conduct an interview to determine:

- New or worsening symptoms
- New or worsening medical conditions and health related events that take place while you are in the study. This may include things such as an injury, another illness, pregnancy and even side effects that you are experiencing since starting the study drug.
- New or changes to medications or herbal products and supplements
- Information about potential on-going COVID-19 exposures

Note that interviews will be conducted in-person or remotely (telephone, video-conferencing e.g. Zoom) at Days 7, 14, 35 and 90.

Diaries:

All participants will be asked to complete a daily symptoms diary from days 2-14 and a weekly symptoms diary for 3 weeks after that. This symptom diary is a simple checklist about the severity of any symptoms you may have. This dairy includes a temperature check. You will use the thermometer you were provided with in the study kit to check your temperature and record it in the diary. If you are in the 'active' arm of the study, you will also be asked to complete an adherence diary daily for the 14 days that you are taking study drug. The adherence diary will help determine to what degree you are taking the study drug as instructed. Study staff will instruct you on how to complete the diaries online, using the Research Electronic Data Capture system (REDCap), through an email link that will be sent to you daily from days 2-14. If you are unable to access the internet, paper versions will be provided to you in your study kit.

Questionnaires:
You will also be asked to complete questionnaires on Days 1, 14, 21, 28, 35 and 90, using REDCap through an email link that will be sent to you. Study staff will instruct you on how to do this. If you are not able to complete questionnaires online then study staff will assist you in completing them over the telephone. Regular e-mail and/or telephone reminders will be provided to remind you to complete questionnaires.

The Day 1 questionnaire will collect information on your demographics (eg. age, race, gender), your HIV testing experience (active arm only) and your quality of life (your physical ability to move, ability to take care of yourself, ability conduct your usual activities, pain and discomfort levels, and any feelings of anxiety and depression you may be having). In addition to questions about your quality of life, Day 14 will ask about psychological stress, Days 21, 28 and 35 will ask about additional symptoms and COVID-19 exposures, and Day 90 will ask about the longer-term impact of your COVID-19 exposure.

HIV self-testing:
Active arm participants will be provided with a home HIV testing kit to be used on Day 1. Although this test kit has not been approved for general use in Canada, it has been approved by Health Canada for use in this study through the Special Access Programme. This is required because use of the study drug Kaletra® in those with undiagnosed HIV is not sufficient for actual HIV treatment. Study staff will perform routine pre-test counseling with you and guide you through the steps of self-testing. This will be done remotely via face-to-face video and only if necessary, by telephone. If your HIV self-test is positive, you will receive counseling and support, and you will be immediately linked to an HIV specialist who will do a standard blood test to confirm the diagnosis. If this blood test is also positive for HIV, study staff are required by law to report the result to local public health authorities.

Dried blood spot:
Active arm participants will be provided with materials to do a finger prick and then collect a couple drops of blood onto a paper card on Day 1. A randomly selected group of active arm participants (about one-quarter of them) will do this again on Day 14. These samples will then be used to check for COVID-19, and for levels of the study drug. Participants will be asked to bring them in at the Day 35 visit.

Self-collected nasal swabs:
You will be provided with printed instructions and a video demonstration on how to self-collect, label, date and package a nasal swab to test for COVID-19. Swabs will be done with the support of study staff, who can walk you through the process via video link, telephone or in person on Days 1, 7 and 14. You will also be asked to collect a swab if you develop COVID-19 symptoms. These samples will be sent to either Sunnybrook Health Sciences or Mount Sinai Hospital for testing. If your baseline nasal swab confirms COVID-19, you can continue the study drug and still remain in the study and complete all other relevant study procedures. You will be informed of the results of your COVID-19 tests as soon as possible after they become available, and within 24 hours of study staff learning about a positive result. If any of your swab tests are positive for COVID-19, study staff are required by law to report the result to local public health authorities. You will be provided with counselling and support to help you through this diagnosis and you will be linked to appropriate care as required. You will also be allowed to continue taking study drug if you are in the 'active' arm of the study.

Biological Samples for Research Use:
Approximately one teaspoon of blood will be collected at the in-person visit on Day 35 and possibly Day 1. These samples will be stored at Dr. Samira Mubareka's lab at Sunnybrook Hospital and tested for COVID-19 once a blood test for COVID-19 has been developed. The randomly selected group of active arm participants who do the second dried blood spot will also

have one teaspoon collected at the Day 35 visit for a complete blood count (measurement of red and white blood cells) because this is needed to understand the study drug levels.

Biological Samples for Future Use:
We would also like to ask you to consider allowing us to store two teaspoons of your blood samples for use in the future. Blood samples may be used to study other respiratory viruses and immune system-related function. You do not need to agree to the optional storage and use of your samples in order to take part in this study. These samples will be stored for a maximum of 10 years, at which point any unused samples will be destroyed.

How will samples be identified?
Your samples will only be identified using a code number, and handled in a confidential manner.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Tell the study doctor about your current medical conditions; new and worsening
- Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbal products, and check with the study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the study drug Kaletra® that you may receive in the active arm of this study.
- Tell the study doctor if you are thinking about participating in another research study
- Follow instructions to complete all study procedures include self-tests (HIV, swabs), completing questionnaires and diaries, etc.
- Cooperate with the study staff to ensure receipt of medication by courier and availability for completion of study visit procedures (remote and in-person)
- Tell the study doctor if you become pregnant
- Use Kaletra® only as instructed. Remember study drug is for you alone, and must not be shared with others
- Maintain self-quarantine for 14 days. 14 days is the incubation period of COVID-19.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Total study duration for each participant is 90 days as outlined in detail in the Study Procedures section above. The Day 1 visit may take up to 1.5 hrs and the Day 14 visit may take up to 1 hrs each while the screening, Day 35 and Day 90 visits are expected to take 45 min. On average, study visits (whether remote or in-person) are expected to take one hour each.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Your participation in the study is voluntary. You may choose to stop taking part in the study at any time, without giving a reason. Your decision will not affect your medical care now or in the future. It will not affect other benefits you receive outside of the study. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff. You may be asked questions about your experience with the study intervention, and to have laboratory tests and physical examinations considered necessary to safely stop your study involvement e.g. completing testing for COVID-19. You can request to withdraw your stored samples at any time up until they are used for testing. All samples that have not been tested already will be destroyed after 10 years.

If at any time you choose to withdraw from this study or have your samples withdrawn, please contact a member of the study team. Information that was recorded before you withdrew will be

used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation in the study may be stopped without your consent for the following reasons:

- If continuation in the study appears to be harmful to you;
- If it is discovered that you do not meet the eligibility requirements

The study may be stopped by the investigators or by the study sponsor at any time for any reason. If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study. In the rare circumstance that you have to stop study drug due to drug interactions or side effects, you will be asked to remain in the study and complete all other study procedures for your safety.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from the study drug, Kaletra®. Some side effects are known and have been listed in the study drug section. Most side effects have been recognized in the context of HIV treatment or PEP, when taken in combination with other anti-HIV medications. A previous study in adults hospitalized with severe COVID-19 found gastrointestinal adverse events including nausea, vomiting, and diarrhea were more common with Kaletra®, occurring in 4-6% of patients.

Kaletra has rarely been linked to abnormal heart rhythms in people with certain genetic conditions and in people taking specific medications. The study team will review this with you, and may recommend doing a heart tracing if needed.

You may feel anxiety, panic, distress or other strong emotions due to the questions in the study questionnaires. You do not have to answer any questions you do not want to. In your study package you will be provided with a list of mental health resources (e.g. counselling services). Study staff will be in touch with you regularly and several study procedures including interviews and questionnaires will address the psychological and functional impacts of your COVID-19 experience.

When you give blood you may feel faint, or experience mild pain, bruising, irritation or redness at the site. In rare cases, you may get an infection.

Risks of Electronic Communication: E-mail, Text Messaging and Video-link

There are significant risks associated with electronic based communications, including:

- Your privacy cannot be completely guaranteed during a video-link based communication. Study staff will use Zoom for Healthcare, an encrypted platform for video conferencing but security measures on your end cannot be guaranteed.
- Videos can be recorded by a third part or by malware installed on devices
- The privacy and security of your text and email communications cannot be guaranteed. If someone sees the texts you send and receive, they may be able to tell that you may have or are at high-risk of having COVID-19
- Phone providers may have a legal right to inspect and keep texts passing through their systems
- Email may carry computer viruses that may damage computer data or software or disclose my information against my wishes.

- Electronic communications can be intercepted, forwarded, circulated, stored or even changed without the knowledge or permission of either the sender or recipient.
- Copies of electronic communications may continue to exist, even after reasonable efforts to delete them
- Electronic communications may be accidentally sent to an unintended recipient, or to many such recipients.
- Electronic communications may be disclosed to third parties or to the public, regardless of the intentions of the receiver or sender.

WHAT ARE THE REPRODUCTIVE RISKS?

There are no restrictions regarding pregnancy. There is considerable experience with the use of Kaletra® in pregnancy among people living with HIV who have taken the drug regularly and for long periods of time. Kaletra® should not be taken if you are breastfeeding.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Taking part in this study may or may not have direct benefit to you. The use of Kaletra® as COVID-19 PEP in this study is experimental, as it has not been proven to be effective at preventing COVID-19. Knowledge from this study may help doctors better understand COVID-19 and prevention options. Data from the study may help determine who is more likely to benefit or who is more likely to have side effects from the study drug so that it may also help future patients. When the study is completed at all the study sites and the data is analyzed and reported, you will have an opportunity to learn of the results. You may ask your study doctor for the results and to have them explained to you.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study. All persons involved in the study, including the study investigators, coordinators, nurses, monitors and delegates (hereby referred to as 'study staff'), are committed to respecting your privacy. Aside from the study staff, authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Applied Health Research Centre (AHRC)
- The Research Ethics Board who oversees the ethical conduct of this study in Ontario
- Toronto Public Health Research Ethics Board
- Health Canada (because they oversee the use of medications in Canada)
- This institution and affiliated sites, to oversee the conduct of the research at this location

Records identifying you 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. To protect your privacy, no information that discloses your identity will be released unless required by applicable laws. It is important to note that positive results for transmittable infections such as COVID-19 are HIV are required by law to be reported to Public Health, as per the Health Protection and Promotion Act. Please also be advised that if there is evidence of clear and imminent danger or harm to yourself and/or others, the study personnel are required to dissolve your confidentiality and report to relevant authorities. Study personnel will also enlist appropriate medical assistance, where you will be asked to seek or be referred for medical care.

The study personnel and the study sponsor will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario.

All of your study data and samples will be coded with uniquely numbered identifiers. Your coded data will be stored using the Research Electronic Data Capture system (REDCap) housed on secure servers at the Applied Health Research Centre (AHRC) at St. Michael's Hospital. Linking your study data to you is only possible through a code list. The code list is kept secure and confidential by the study site. Information that directly identifies you will not leave the study site or be sent to the Sponsor.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your disclosed identifiers e.g. participant code, initials, sex, and date of birth.

Only encrypted tele-health systems and encrypted emails on the part of the study sites and staff will be utilized for communication, consent and completing study procedures. However, communication via your personal e-mail and text messaging through your personal cellular phones is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail or text messaging.

In the event of death, we may be required to send de-identified information about your death to the drug manufacturer.

Data essential to study participation may also include the following personal health information:

- Your name, address, telephone number, health card and hospital medical record number(s) where applicable.
- Your age, gender, ethnic and racial background.
- Lifestyle information; health and medical history, physical exam findings, lab test results.
- Your response/ side effects to study drug and possible other treatments provided
- Data resulting from testing your biological samples.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The study staff will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small. Any medical issues or concerns relating to your safety that are detected during the course of the study will be reviewed by the Research Team and Study Doctor. If any medical issues require additional attention, appropriate referrals will be made on your behalf.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial is available on http://www.clinicaltrials.gov, as required by Canadian best practices. This website will not include information that can identify you. At most, it will include a summary of the results. You can search this Web site at any time.

When the results of this study are published, your identity will remain confidential. Only your de-identified data will be shared in public repositories that promote open access publishing. Open access is a set of principles that promote the sharing of research data and outcomes openly for the research community and the public, to advance knowledge. Dryad is an example of an open access repository.

WHAT IS THE COST TO PARTICIPANTS?

The study drug Kaletra® will be supplied at no charge while you take part in this study. The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available. Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study. In the case of research-related side effects or injury, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigators, study sponsor or involved institutions from their legal and professional responsibilities.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete. The results of this study will be available on the clinical trial registry (see the “Will information about this study be available online” section for more details).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form you do not give up any of your 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.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During or after the study, the researchers may learn something about you that they didn’t expect. For example, the researchers may find out from testing of your samples that you have another condition. If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. Darrell Tan	(416) 864-5568
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can contact the Research Ethics Board.

Unity Health Research Ethics Board	(416) 864-6060 x 42557
Board of Record	Telephone and Hours

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

_____	_____	_____	_____
Signature of Participant/	PRINTED NAME	Date	Time (am/pm or 24hr clock)

I agree, or consent, that my child _____ *may take part in this study.*
Name of Child Participant

_____	_____	_____	_____
Signature of Parent/ Legal Guardian	PRINTED NAME of Parent/ Legal Guardian	Date	Time (am/pm or 24hr clock)

_____	_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date	Time (am/pm)

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please complete the signature space below:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

_____	_____	_____
PRINT NAME of witness	Signature	Date