Appendix 1.

Main Informed Consent Form

Version 2.1
July 27, 2022

INTRODUCTION
You are being invited to take part in this research study because you are living with the Human Immunodeficiency Virus (HIV) and you are taking anti-HIV medication.

Before you decide to take part in this study, it is important that you read and understand the following explanation about the study and its risks and benefits. This form may contain words you do not fully understand. Please ask the study doctor or study team to explain anything you do not understand and make sure that all your questions have been answered. You may also want to discuss this study with your family doctor, a family member or close friend before you make your decision about taking part. Being in this study does not replace your regular medical care.

If you decide to take part in this study, you will be asked to sign this form and a copy will be given to you.

BACKGROUND
Antiretroviral therapy (ART) is able to manage your HIV infection and help improve your health and quality of life. However, even when ART is taken correctly people living with HIV are at higher risk of developing certain inflammatory-related health conditions including diabetes, fatty liver, cardiovascular disease, brain-health related diseases and cancer. Essentially HIV keeps immune cells in an active or inflammatory state, partly due to the damage HIV does to the gut.

The lining of the gut acts as a barrier and prevents undesirable gut contents (e.g. bad bacteria) from traveling through the gut lining and into the blood. These gut compounds entering the bloodstream trigger inflammation and over time can increase the risk of inflammatory-related health conditions. ART medication can help repair some of the damage caused by HIV, however ART does not reduce the number of bacterial compounds crossing the gut lining to levels seen in healthy HIV-negative people. There is a need to find therapies to decrease this chronic inflammation in people living with HIV.

In addition to HIV itself, co-infection with other viruses such as the **cytomegalovirus (CMV)** has been shown to enhance inflammation in people living with HIV. CMV is a very frequent virus, which is usually well tolerated during acute infection. However, similarly to HIV, this virus has the ability to persist lifelong, mostly in deep tissues such as the gut and lymph nodes. Although the infection remains mostly silent if the immune system is strong, CMV chronic infection perturbates the immune system, induces inflammation and increases leaky gut. This virus has also been shown to decrease the immune response against other pathogens, and also to impair the response to vaccines.

We want to explore how CMV increases inflammation in tissues of people living with HIV taking ART. In this study, we will try to inhibit CMV with a new and specific drug called letermovir, in order to decrease leaky gut markers and inflammation. Conversely to previous

anti-CMV drugs, this new medication is very well tolerated, and is also very efficient in preventing CMV.

PURPOSES OF THE RESEARCH STUDY
The main purpose of this study is to evaluate if taking tablets of letermovir (Prevymis ®) in addition to your ART medications will reduce inflammation and leaky gut. There will be one group of participants who will receive the drug, and another group receiving only their usual ART, as a control. By comparing the two groups, we will evaluate if letermovir is able to reduce inflammation, leaky gut and also to decrease the markers of CMV silent infection.

Optional sub-study (Montreal site only)
Participants at the Montreal site that agree to take part in this study will be invited to take part in an optional sub-study that will involve colon biopsies before and at the end of the study. The purpose of the sub-study is to directly assess changes in gut mucosa. The mucosa is the lining of the gut which helps stop pathogens from entering the body. The sub-study will be explained in a separate informed consent form.

BRIEF STUDY DESCRIPTION
A total of 60 participants will be enrolled in this study from up to four sites in Canada.

You will be asked to come to the clinic for a screening visit. You will be assessed to see if you meet the eligibility criteria to take part in the study. Once you are confirmed to be eligible to take part in the study, your participation will last about 26 weeks, not including the screening visit. At the beginning of the study, you will be informed if you have been randomized in the group of participants receiving letermovir in addition to their ART or receiving ART only. Over the course of the study, you will be asked to come to the clinic for 7 visits and you will be asked to give blood and stool samples. You will be asked to take either the study treatment, Prevymis ®, or only your usual ART, for 14 weeks. In total, your participation will take about 5-6 hours over the duration of the study.

STUDY INCLUSION CRITERIA
To be eligible for the study you must be 18 years of age or older, be CMV positive, be HIV positive, be on ART for at least 3 years, and on the same ART medications for at least 3 months. If you are taking statin medication, the dose of your statin will be reduced by 50% for the duration of the study. You must have an undetectable viral load (the quantity of HIV virus in your blood must be less than 50 copies/ml, except for one blip not higher than 200 copies/ml per year in the last 3 years) for at least 3 years and have a CD4 count of more than 400.

STUDY EXCLUSION CRITERIA
You will not be able to take part in the study if you have an active co-infection with Hepatitis B or C virus, or if you have any underlying conditions, such as diabetes, cardiovascular disease or renal dysfunction. Your study doctor or nurse will review your medical history with you and make sure you do not have a health condition that will exclude you from the study.

Some drugs and herbal supplements such as immunomodulatory drugs: methotrexate, antibiotics, metformin, morphine and derivatives, aluminum containing phosphate binders, chemotherapeutics, niacin, anticoagulant (including Warfarin, Coumadin® and Jantoven®), pimozide, ergot alkaloids, and cyclosporine are banned during the study because of known interactions with letermovir. Regarding HIV medication, darunavir, efavirenz, etravirine and nevirapine will also be banned due to interactions. During the screening visit, please tell the

study nurse or doctor about any prescription drugs, natural health products (including supplements or herbal products), pre- or probiotics or other non-prescription drugs (including cannabis and street drugs) that you are taking or plan on taking. Alcohol is not banned, but participants will be screened using an alcohol questionnaire (AUDIT, see details below) and excluded if alcohol abuse is suspected. Those with pre-existing conditions that could prevent study compliance such as street drug abuse or psychiatric illness will be excluded at the discretion of the study doctor.

You will not be able to take part in this study if you are currently participating in another clinical trial or have done so in the past 3 months.

Females who are pregnant, planning on becoming pregnant, or who are breast-feeding will be excluded from the study.

STUDY MEDICATION

Eligible participants in the medication group will be asked to take either 1 tablet of 480mg or 2 tablets of 240mg of Prevymis ® (letermovir) orally once a day, at about the same time each day, for 14 weeks.

Prevymis ® is an anti-CMV drug that inhibits the correct formation of the viral particles. This drug has been approved since 2017 for the prevention of CMV infection in persons receiving a bone marrow transplant, who suffer from frequent infections.

Prevymis ® is approved for this latter use by Health Canada, but in this study, it will be used outside of its approved label claims, in an experimental manner.

Prevymis ® will not be provided to you after the study is completed. The goal of this study is to understand CMV and how it affects inflammation and the gut rather than testing letermovir itself. Larger studies will be required to establish if letermovir should be prescribed lifelong in people living with HIV. If you withdraw from the study without completing the study, we will ask you to return any unused study drug.

STUDY VISITS AND PROCEDURES

The study visits and procedures are summarized in Table 1 and described below.

Screening Visit: Week -8 to Week -2 (1 hour 30 minutes)

Up to six weeks prior to being enrolled into the study, you will be asked to come to the clinic for a screening visit. You will undergo the following procedures to determine if you are eligible to take part in this study.

- You will be asked to sign this informed consent form if you agree to take part in this study
- You will be asked about demographic information and your medical history including
    - Age, education, ethnicity, sexual preference
    - Past and current illnesses
    - Medications or supplements that you are currently taking or have taken recently, including a review of ART history
    - Review an acceptable method of contraception
- You will undergo a complete physical examination including measurement of your vital signs (blood pressure, temperature, respiratory rate and heart rate) and weight and height

- A blood sample (about 20 ml or 1½ tablespoons) will be collected for routine blood work:
  - to determine if you are CMV positive
  - to measure the amount of HIV in your blood;
  - to determine CD4 and CD8 T cell counts;
  - to measure the level of your blood cells
  - to perform serum chemistry tests, including tests to see how your liver and kidneys are working and the level of fats in your blood (e.g. cholesterol) and to test for diabetes
  - to test for Hepatitis B and C
    - Hepatitis B and C: by signing this consent, you agree for the study team to perform these tests. The study doctor or study staff will tell you if the test results are positive. Positive result(s) testing are reportable to local health authorities in Quebec. If you have active Hepatitis B or C, you may not be able to participate in the study but you will be linked to a specialized doctor for appropriate care.
  - to test for pregnancy (for women of childbearing potential)
- Study staff will administer a questionnaire about your alcohol use
- You will be provided with a stool collection kit and instructions for collecting a stool sample in the 24 hours before your next visit

The study doctor will review the information collected about you and your test results and if you meet the eligibility criteria to take part in the study you will be contacted to attend a Baseline visit.

To prepare for your study visits we ask that you:
- Do not take any non-prescription drugs in the 48 hours before each study visit
- Do not use marijuana products in the 24 hours before each study visit
- Do not consume alcohol in the 24 hours before each study visit, except for one drink (optional) at the previous night's meal

Baseline and Follow-up Visits (Week -2, Week 0, Week 2, Week 4, Week 14, and Week 26)
If you are eligible and agree to take part in this study, you will be asked to return to the clinic at the start of the study (***Week -2***), and subsequently at ***Week 0*** *(start of treatment visit),* ***Week 2*** *(on treatment visit),* ***Week 4*** *(on treatment visit),* ***Week 14*** *(end of treatment visit)* ***and Week 26*** *(final study visit)*. If you are randomized in the letermovir group, you will be asked to take this drug for 14 weeks starting at Week 0 and you must continue to take your anti-HIV drugs during the whole study period (e.g. from Week -2 to Week 26). If you are randomized in the control group, you will be asked to take your anti-HIV drugs only for the whole study period. Each study visit will take approximately 30 minutes to 1 hour.

Please remember to bring your stool sample (collected in the 24 hours prior to the study visit) at Week -2, Week 0, Week 2, Week 4, Week 14 and Week 26.

During the Baseline and Follow-up visits, you will undergo the following procedures:

- You will be asked to confirm your ongoing consent.
- Starting at Week 0, you will be provided with a supply of study drug, letermovir, sufficient to last until your next study visit.
- At Week 0, you will be given a daily Dosing Diary to help you to remember and track taking your study drug.

- You will be asked about any changes in health and any medications (including prescription drugs, (e.g., anti-HIV ART), non-prescription medications), acceptable method of contraception, supplements, vitamins, cannabis products, and street drug use you are taking or have taken.
- Adverse event(s) will be assessed.
- Study staff will administer a questionnaire about your alcohol use and differences in bowel movements during the study.
- You will undergo a targeted physical examination including measurement of vital signs and weight.
- A blood sample (about 20 ml or 1½ tablespoons) will be collected for routine blood work:
    - to measure the amount of HIV in your blood;
    - to measure the amount of CMV in your blood;
    - to determine CD4 and CD8 T cell counts;
    - to measure the number and percentage of your blood cells;
    - to perform serum chemistry tests, including tests to see how your liver and kidneys are working and to measure the level of fats in your blood (e.g. cholesterol);
    - to test for Hepatitis B and C, and cytomegalovirus infections (Week 0);
    - to test for pregnancy (for women of childbearing potential).
- A blood sample (about 100 ml or 7 tablespoons) will be collected for analysis of your immune system (e.g. biomarkers, inflammatory markers)
- Study staff will collect the stool sample from you. This sample will be used to assess the effect of letermovir on the types of bacteria in your gut. You will be provided with a stool collection kit and instructions for collecting a stool sample in the 24 hours before your next visit.
- At Week 2, Week 4 and Week 14 study staff will administer a questionnaire about your compliance to the study medication and study staff will count the pills you have not taken. **Please remember to bring your Prevymis® bottles and Dosing Diary to the Week 2, Week 4 and Week 14 visits**.

The research team will consult your medical file to collect information related to your medical history and record relevant data for this research project. We will also access your personal medical data in the provincial database/registries of the provincial database Dossier Santé Québec (DSQ) to be able to link data collected from this study. Newly diagnosed Hepatitis B and C infections will be notified to the local health authorities in Quebec as nationally notifiable diseases. This information will confirm medical diagnoses, medications and in the event of death, details on the cause of death as well as any tests and exams done before the event.

Taking letermovir (Prevymis®)

At Week 0, Week 2, and Week 4, you will be given a supply of **Prevymis®** sufficient to last until your next study visit, and instructions on how to take it. Begin taking the study medication on the day you receive it and continue to take the study medication as instructed. Remember to promptly record each dose of Prevymis you take in the daily Dosing Diary provided.

Visit Scheduling

To ensure adequate follow-up during your study participation, the study staff will contact you by a way that is agreed upon by you and the study staff (e.g., email/phone) during the Screening visit. If you miss a study visit, clinic staff will try to contact you to reschedule your visit. Please contact the study staff if you are unable to attend a scheduled appointment so that the visit can be rescheduled. Clinical research staff trying to contact you will be careful to maintain your

privacy and will not tell anyone, without your permission, about your participation in this HIV study.

Table 1: Schedule of Visits and Procedures

Visit Type	**Screening**	**Study Visits**					
		Baseline 1	**Baseline 2**	**Treatment**			**Post-treatment**
Visit Window **Procedures:**	***Week -4 to -1*** **(±7 days)**	**Week -2 (±7 days)**	***Week 0*** **(Day 0)**	**Week 2 (±3 days)**	**Week 4 (±3 days)**	**Week 14 (±7 days)**	**Week 26 (±7 days)**
Visit No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Informed Consent	X						
Oral re-consent		X					
Eligibility Assessment	X	X	X				
Concomitant Medication	X	X	X	X	X	X	X
Medical History	X						
Complete Physical Exam and Vital Signs	X						
Targeted Physical Exam and Vital Signs		X	X	X	X	X	X
Adverse Event Assessment		X	X	X	X	X	X
Serum Pregnancy Test	X	X	X	X	X	X	X
Hematology	X	X	X	X	X	X	X
Serum Chemistry	X	X	X	X	X	X	X
Serology	X		X				
Serology - HIV-1 Viral Load	X	X	X	X	X	X	X
Markers of gut barrier integrity, inflammation and microbial translocation		X	X	X	X	X	X
Immune activation markers/cytokines (ELISA)		X	X	X	X	X	X
Monocyte and T cell activation markers		X	X	X	X	X	X
Anti-CMV IgG and IgM in Serum, anti-CMV CD4 and CD8 T-cells in PBMC, CMV DNA in plasma and PBMC		X	X	X	X	X	X
Size of HIV reservoir in Latently Infected CD4 T cells		X	X	X	X	X	X
Stool sample collection and microbiota composition		X	X	X	X	X	X
Alcohol use (AUDIT-Full),	X						
Alcohol use (AUDIT-C),		X	X	X	X	X	X
Bristol score questionnaire,	X	X	X	X	X	X	X
Provision of Dosing Diary			X				
Study Product Dispensation			X	X	X		
Study Product Compliance				X	X	X	
Collection of Dosing Diary				X	X	X	

Results of routine blood work, including measurements of HIV viral load and CD4 T-cell counts, will be communicated to you in "real time" (without delay) so that you and your doctor can act quickly on the information.

POTENTIAL RISKS AND/OR DISCOMFORTS
Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in humans to date. Please call the study doctor or study staff if you have any side effects, even if you do not think it has anything to do with this study.

Risks associated with letermovir
The most frequently reported side effects of letermovir are:

- nausea (1.6%),
- vomiting (0.8%), and
- abdominal pain (0.6%).

These symptoms are usually mild, transient, and reversible after discontinuation of the product. Moreover, in rare cases, cardiac arrythmia (tachycardia) has also been reported. If you feel any palpitation, shortness of breath or chest pain, you should immediately contact your physician or an emergency unit.

Risks associated with blood draws
Less than 1% of individuals who have their blood taken experience any side effects; these side effects may include discomfort, bleeding, or bruising where the needle enters the body.

Reproductive risks
Limited information is available regarding the safety of letermovir in pregnant or breast-feeding women. For this reason, women who are pregnant, are planning to become pregnant, or lactating women will be excluded from this study. If you become pregnant during your participation in this clinical study, letermovir should be discontinued right away. **Please contact the study doctor or study staff immediately if you think you have become pregnant during the study**.

Participants in this study will need to follow the following guidelines for prevention of pregnancy.

Birth Control: ***Acceptable Methods of Birth Control***
Women of childbearing potential must agree to use one of the following approved methods of birth control while in the study and until 2 weeks after completion of the study:

a. Complete abstinence from penile-vaginal intercourse from the screening period until 2 weeks after study completion.
b. Double barrier method (acceptable barrier methods include diaphragm, coil, contraceptive foam, sponge with spermicide, or condom).
c. Oral, injectable or implant contraceptives, started at least 30 days before screening, plus one barrier method.
d. Any intrauterine device (IUD) with published data showing that the expected failure rate is <1% per year (not all IUDs meet this criterion) plus one barrier method.
e. Male partner sterilization confirmed prior to the female participant's entry into the study; this male is the sole partner for that participant.

f. Another method approved by the Investigator with published data showing that the expected failure rate is <1% per year preferably with one barrier method.

Any contraception method must be used consistently, in accordance with the approved product label, and for the duration of the study and until two weeks after study completion.
Women of non-child-bearing potential as defined as either post-menopausal (12 months of spontaneous amenorrhea and ≥ 45 years of age) or physically incapable of becoming pregnant with documented tubal ligation, hysterectomy or bilateral oophorectomy.

Sexually active men with a female partner of childbearing potential must agree to one of the following methods of birth control during the study and for 2 weeks after study completion:
a. The use of at least one barrier method of contraception (e.g. condom) with a female partner using a second approved method of contraception (IUD, hormonal contraceptive pill, diaphragm, spermicide, etc.) during the study and until two weeks after study completion.
b. Have had a successful vasectomy.
c. Be confirmed sterile.

Contraceptive measures will be reviewed with participants at all study visits over the course of the study.

Drug-drug interactions
Some drugs will interact with letermovir and should be avoided during the study. For a complete list, see “STUDY EXCLUSION CRITERIA”.

Alcohol Consumption
Alcoholic beverage consumption has been linked to increased inflammation and a leaky gut in HIV-infected population. A leaky gut is a condition in which bacteria and toxins are able to "leak" through the intestinal wall. Alcoholic beverages should be avoided, or limited to one per day (preferably less than daily use), during the study. Regular or excessive use may mask any positive effects of letermovir on reducing inflammation and could potentially increase the risk of diarrhea. An alcohol use questionnaire (AUDIT) will be conducted during screening to exclude those with potential alcohol abuse problems. At subsequent study visits, a shortened alcohol use questionnaire will be used to monitor differences in alcohol consumption between participants in case this becomes a differentiating/group-defining factor.

POTENTIAL BENEFITS
We do not know whether taking part in this study will benefit you. What we do learn from this study may benefit other people living with HIV in the future.

RETURN OF RESULTS
At the end of the study, you will be told when study results will be available and how to learn about them. Individual research results from sample analyses will not be returned to you or to your physicians.

INCIDENTAL FINDINGS
Significant incidental findings are unexpected findings made during the course of the study that may affect your current or future wellbeing or that of your family members. If, in the course of this study, we discover evidence of a significant finding we will communicate this to you and to a health professional of your choice. You may then use this information to make a decision about continuing to participate in the study.

ALTERNATIVE TO BEING IN THE STUDY

If you do not want to take part in this study that combines ART with letermovir treatment, the current standard of care for a person infected by HIV is ART alone. You do not need to be in this study to receive treatment for HIV. If you decide not to enter this study, there may be other choices available. Please ask the study doctor to discuss these options with you. You will be advised of any changes to the HIV treatment guidelines that occur during the course of this study.

CONFIDENTIALITY

During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from your medical chart, including your identity, concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project. Your research file could also contain other information, such as your name, address, phone number, health plan number, sex, date of birth and ethnic origin. All personal information obtained during this study will be kept strictly confidential. The study doctor will store your study data for 15 years in accordance with Health Canada requirements, after which time it will be destroyed.

All the information collected during the research project will remain strictly confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept under lock and key by the study doctor. The study doctor will forward your coded data to the Sponsor-Investigator or their representatives for the exclusive objectives of this study. This data will be stored for 15 years and then destroyed.

To ensure your safety, a copy of this information and consent form will be placed in your medical chart. As a result, any person or company to whom you give access to your medical chart will have access to the information in this form.

The study data may be published or shared during scientific meetings; however, it will not be possible to identify you.

Your medical charts may be examined by a person mandated by Canadian authorities, such as Health Canada, as well as by representatives of the study sponsor-investigator, the institution, or the Research Ethics Board for the purposes of monitoring the study, ensuring patient safety, and assessing compliance with applicable regulations. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

COSTS

There will be no cost to you for participating in this study. All clinical and professional services, diagnostic and laboratory tests that are part of this study will be provided to you at no cost. If you are randomized in the letermovir group, the study medication, letermovir will be supplied to you at no cost. You will continue to obtain your other anti-HIV treatment by prescription; this medication will be paid for either by a government drug program or by your own insurance.

COMPENSATION
You will receive an amount of $60.00 per study visit, for a total of 7 visits, for a total amount of $420.00 for costs and inconveniences incurred during this research study. If you withdraw from the study, or are withdrawn before it is completed, you will receive compensation proportional to the number of visits you have completed.

SHOULD YOU SUFFER ANY HARM
Should you suffer harm of any kind following administration of the study medication, letermovir, or following any other procedure related to the research study, you will receive the appropriate care and services required by your state of health.

By agreeing to participate in this research study, you are not waiving any of your legal rights, nor discharging the study doctor, the sponsor-investigator, or the institution of their civil and professional responsibilities.

VOLUNTARY PARTICIPATION AND STUDY WITHDRAWAL
Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor, the Research Ethics Board, the funding agency, Health Canada, or the Sponsor-Investigator may terminate your participation in the study without your consent, or terminate the entire study. This may happen if new findings or information indicate that participation is no longer in your best interest, if you do not follow study instructions, or if there are administrative reasons to terminate the study. In addition, your participation in the study could be terminated by your doctor due to study medication side effects, failure to take the study product as indicated, failure to come for study visits or termination of the study. If you are asked to leave the study, the reasons for this will be explained to you.

However, for safety reasons, before you withdraw from the study, we ask that you attend the clinic for a safety follow-up visit. You will be asked about any side effects you may have experienced, any medication you are taking or have taken. You will be asked to return any unused letermovir. You may be asked to provide a blood sample for routine blood work.

During the course of the study, you will be kept informed of any new treatments or findings that may influence your decision to continue participation in the study.

If you withdraw or are withdrawn from the study, the information and biological material already collected for the study will be stored, analyzed and used to ensure the integrity of the study.

Any new findings that could influence your decision to stay in the research study will be shared with you as soon as possible.

STORAGE AND USE OF BIOLOGICAL SAMPLES

Your blood and stool samples contain several types of cells that will not be possible to analyze immediately after collection. These expensive analytical tests will be performed in batches with samples from other participants. Your collected samples will be stored under the supervision of Drs. L. Royston, S. Isnard and J.-P. Routy at the Research Institute of the McGill University Health Centre, Glen site, 1001 Decarie Blvd, Montreal, QC, H4A 3J1. Samples will be labelled with a study code and no identifying information. If any of your samples are not needed for the analyses, the storage period for your leftover samples will be 10 years, after which they will be destroyed. During this period, you can ask Dr. Royston or Dr. Routy to withdraw your stored samples. Only the co-investigators and collaborators who will perform the analyses will have access to your samples. Blood samples will be used only for the purposes of this HIV research study. No genetic nor additional tests will be performed outside of the scope of the study without additional consent. Products extracted from your blood or stool samples may be sent to Dr. Marette's lab in Quebec City, QC, or Dr. Chomont's lab in Montreal, QC, for analysis. Those samples will be labelled with a study code and without any identifying information.

FUNDING OF THE RESEARCH PROJECT

This study is being funded by the Canadian HIV Trials Network (CTN) and by Merck Canada Investigator Studies Program (MISP). Merck will be providing the study drug in-kind during the whole study. The study will be run by Dr Jean-Pierre Routy. The sponsor-investigator has received funding for conducting this research study.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

CONTACT INFORMATION

If you have questions or if you have a problem you think may be related to your participation in this clinical research study or you would like to withdraw, you may communicate with Dr Jean-Pierre Routy during working hours at **514-843-2090** or with the study coordinator at **514-934-1934 Ext. 34240**. After working hours, call 514 934-1934, Ext. 53333 and ask for the physician-on-call for the McGill University Health Centre.

If you have questions concerning your rights as a research participant and wish to discuss them with someone not connected to the clinical research study, please contact the **Ombudsman of the McGill University Health Centre at (514) 934-1934 extension 35655**.

CONTROL OF ETHICAL ASPECTS OF THE RESEARCH PROJECT

The Research Ethics Board of the McGill University Health Centre has given ethics approval to this research study and is responsible for its ongoing ethics oversight at all participating institutions in the health and social services network in Quebec.

Study Title: Influence of a 3-month letermovir treatment on gut inflammation in ART-treated HIV-infected persons in an open labelled controlled randomized study

PARTICIPANT INFORMED CONSENT
SIGNATURE PAGE

Signature of the participant:
I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above, understanding that I may withdraw my participation at any time.

I authorize the research study team to have access to my medical record for the purposes of this study.

Name of Participant (printed)	Signature of Participant	Date of consent dd mmm yyyy

Signature of the person obtaining consent:
I have explained the research study and the terms of this information and consent form to the research participant, and I answered all his/her questions.

Name of person obtaining consent (printed)	Study Role of the person obtaining consent
Signature of person obtaining consent	Date of consent dd mmm yyyy