



INFORMATION AND CONSENT FORM

Title: Understanding and Optimizing Brain Health in HIV Now

Principal Investigator: Dr. Graham Smith

Study Site: Maple Leaf Medical Clinic

Sponsor: McGill University
Canadian Institute of Health Research (CIHR)

INTRODUCTION

You are asked to take part in this study because you are over the age of 35 and you have been HIV positive for a least a year.

Before deciding to participate in the study, you should clearly understand its requirements, risks and benefits. This document provides information about the study, and it may contain words you do not fully understand. Please read it carefully and ask the study staff any questions you may have. They will discuss the study with you in detail. You may take this form with you and discuss the study with anyone else before making your decision. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

BACKGROUND

In Canada, the effects of Human Immunodeficiency Virus (HIV) infection on the brain health are unknown. Studies from other countries reported high rates of depression, and problems with memory, concentration or problem solving (cognition). The main component of this study aims to better understand how HIV affects brain health in different people, and how this impacts people's lives. In a group of 900 people with HIV, we will assess several factors that are known to potentially impact brain health. Following the initial evaluation, participants will be followed every 9 months, for 3 additional assessments (total duration of 27 months, 4 assessments) to help us understand how difficulties with mood and cognition develop over time and their impact on every day functioning. Participants will also be eligible for pilot studies of promising interventions aimed at improving brain health.

PURPOSE OF THE STUDY

The purpose of this study is to understand how the Human Immunodeficiency Virus (HIV) affects the brain over time and how this impacts everyday activities. A total of 900 people across Canada will be asked to participate in this study.

STUDY PROCEDURES

The study will continue for 27 months and will involve 4 clinic visits (every 9 months) that may occur at the same time as your regular scheduled doctor’s visits.

If you agree to take part in this study, your participation in the study involves the following: you will be asked to fill out several questionnaires evaluating various factors that can affect brain health and assessing brain health itself (mood and cognition). We will measure cognition with a computerized test. In addition, blood, saliva and urine samples will be taken and some basic clinical measurements will be performed. The blood samples that are not part of your routine medical care will be taken at the initial visit and at your 27 month study visit. You will be required to fast (nothing to eat or drink, except water) for at least 8 hours prior to the blood test. Every 9 months, we will also collect information from routine blood tests done for your HIV care, but you will also be asked to come in fasting for those visits.

You will not be required to take any special drugs as part of the study. You will receive a document on “8 simple steps of how to improve your brain health” to give you information about what you can do now to improve your brain health.

In addition, at one time point to be determined by the central coordination of the study,

- A saliva sample will be collected once at random between your first and last visit and will be used to study differences in people’s DNA and evaluate if there is a genetic component to understanding how HIV affects brain health (*optional- see separate consent*)
- A urine toxicology test to look for the presence of street drugs will be performed once, at random between your first and last visit. This test will be used to validate your responses to questions related to the usage of ‘hard drugs’.

Routine bloods that are part of your medical care will be drawn as usual.

At each visit the following assessments will occur:

	Assessment	Details	Purpose	Time
I	Cognition	This will be done with a computer-based program with the help of the research assistant.	Assess your memory, concentration, attention	30 mins
II	Research Samples	-30 mL (6 tsp) of blood at the same time as your routine blood tests Montreal sites only: an additional 40mL (8 teaspoons) will be collected once at baseline only. -DNA Sample; saliva sample; (<i>optional</i>)	Evaluate biological, immunological, virological and pharmacologic functions related to HIV and cognition Evaluate if there is a genetic component to understanding	5 mins

			how HIV affects cognition	
		<i>The samples will not be made available to any commercial enterprise. Stored samples will be identified only by a code number and will be destroyed after 15 years.</i>		
III	Toxicology test	Urine toxicology test	To detect the presence of street drugs in the body.	5mins
		<i>The urine toxicology test is only for collecting information. The results will not be made available to anyone beyond the research staff. The test will be done only one time between your first and final study visit.</i>		
IV	Clinical measurements	Measure your weight, height, blood pressure, and waist circumference	Evaluate the current state of your health	5 mins
V	Questionnaires	Series of questions to be answered by you	Questionnaires will assess the following aspects of your everyday life, including: <ul style="list-style-type: none"> a) Education and work b) Smoking, alcohol and drug use c) Cognition d) Vitality e) Stress f) Quality of Life g) Illness/Health perception h) Social Support i) Self efficacy j) HIV symptoms k) Depression and Anxiety l) Physical activity m) Sleep 	2 hours

Since the questionnaires are time consuming you will be given several options to complete them. These include completing them on paper, on a computer (on a secure server), at the clinic or another location of your choice (such as home), or over the phone with the research assistant, at a time that has been agreed upon. It is important that no other person answers any of the questions on these questionnaires for you. Depending on the option that you chose, you may be asked to provide your e-mail or mailing address so we can send you the questionnaires.

The total time for each visit is about 3-4 hours. If you decide to complete the questionnaires outside the clinic, the time at the clinic would be 1-2 hours, and 2 additional hours at a later time.

Your responses to these questions will only be viewed by study personnel, and not by anyone involved in your clinical care.

You may be asked to have a full neuropsychological evaluation during a separate session. This evaluation lasts between 1.5 and 4 hours, depending on how difficult the tasks are for you and whether you need time for a break. This is optional (see separate consent form).

In addition, you may be asked to participate in an intervention study aimed at improving different aspects of brain health. With your permission, we would contact you to provide you with information about the intervention studies to which you are eligible, and ask you to participate. A separate informed consent would then be signed.

We will also access your personal data stored in your medical records for information like your blood results, date of HIV diagnosis, treatment history, and medical conditions other than HIV. This information would confirm medical diagnosis and medications.

Use of certain questionnaires that are part of the study require that we send the information obtained during the study to the makers of the questionnaire. The information is shared with them only after all information that could identify you has been completely removed.

RISKS

When a blood sample is taken you may have some slight discomfort at the site of the needle entry and a small bruise may develop.

POTENTIAL BENEFITS

All participants will receive a document on “8 simple steps of how to improve your brain health” to give you information about what you can do now to improve your brain health.

In addition, the information collected may help to gain a better understanding of brain health in people living with HIV and develop treatment interventions.

COSTS

You will not be paid for taking part in this study. However, you will be compensated for your travel and childcare up to a maximum of \$40.00 per visit if you decide to complete the questionnaires at the clinic. If you decide to complete the questionnaires outside the clinic, you will be compensated \$20.00 at the time of your visit and \$20.00, after we have received the completed questionnaires.

INDEMNIFICATION/COMPENSATION IN CASE OF INJURY

If you should suffer any injury following your participation in the research project, you will receive the appropriate care and services for your medical condition without any charge to you.

By accepting to participate in this project, you are not waiving any of your legal rights nor discharging the researchers or the institution of their civil and professional responsibility.

CONFIDENTIALITY

The team of researchers of Maple Leaf Medical Clinic will consult your medical files to take notes of the relevant data to this research project. This may include your name, address, phone number, health plan number, date of birth, medical history, and medical-related information, during your participation in this study.

All information collected for the study will be kept strictly confidential. It will not be included in your medical chart. Should any clinical results be of importance for your medical care, those results will be provided to your physician. Your name will be coded and the code list will be locked at Maple Leaf Medical Clinic with limited access. Data will be stored on a password-protected computer and kept for a period of 25 years and subsequently discarded following the completion of this study. The computer system is operated by a Montreal based third party who will host the data in the province of Québec.

The results from this research study may be published and other physicians participating in this research study may have access to your records related to this research study; however, your identity will not be revealed in the combined results.

In order to verify the research study data, monitors from Veritas IRB Independent Review Board, may review these records.

By signing this consent form, you give us permission to release information regarding your participation in this study to these entities and to the service provider where data will be hosted. Your confidentiality will be protected to the extent permitted by applicable laws and regulations in your Province.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is entirely voluntary, and if you refuse, your medical care and treatment will in no way be affected. If you choose to participate, you may change your mind and withdraw at any time. Again, this will not affect the medical care you receive in any way.

If you no longer wish to share your personal health information, you may cancel your permission at any time by writing to the study doctor. If you cancel your permission during the study, no new personal health information will be collected, and the data gathered to that point will continue to be used to evaluate the study results.

The principal clinical investigators and/or Veritas IRB Independent Review Board are entitled to terminate the study at any time without your consent. If this is the case, you will be given a full explanation.

STORAGE AND SAFEKEEPING OF BLOOD AND DNA SAMPLES

As part of this study, we will be collecting and storing blood samples in order to evaluate how HIV is affecting your immune system; how HIV is responding to the drugs you are taking; how your body's organ systems are functioning and how all these factors are related to cognition. As well, as an optional part of this study, we will be collecting DNA samples (saliva) in order to evaluate if there is a genetic component to understanding how HIV affects cognition.

If you agree to participate in this study, your saliva and blood samples will be stored for up to 15 years after the end of the study. The samples will be stored at the Chronic Viral Illness Service of the Montreal Chest Institute, 3650 rue St. Urbain, Montreal, Quebec H2X 2P4.

Should additional testing be required on your samples, the research team would seek written approval from Veritas IRB Independent Review Board to do so.

The use of your samples or medical information is not intended to provide you or your physician with test results. The study doctor will not make any results available to you, any insurance company, your employer, your family, or any other physician who treats you now or in the future. Research information from this study will not become part of your medical records.

We will protect the confidentiality of your samples. Any personal identification will be coded, upon the assignment of a unique identifier. Scientists working on the sample will only be able to identify a sample by its assigned number but will not know who you are. This unique identifier will be used to store your sample and any corresponding data until the final study report has been written

FUNDING OF THIS RESEARCH PROGRAM

The Canadian Institute of Health Research is providing infrastructure support for the conduct of this research. The study is being conducted by Dr. Marie-Josée Brouillette from the McGill University Health Centre (MUHC). The study doctor is not being paid for including you and looking after you during your participation in this study.

CONTROL OF THE ETHICAL ASPECTS OF THE RESEARCH PROJECT

Veritas IRB Independent Review Board has reviewed this research project and ensures its follow-up. In addition, it will first approve any review and amendment made to the information/consent form and to the study protocol.

QUESTIONS

If you have any questions regarding this research study, contact **Dr. Graham Smith** at **(416) 465-0756**.

This study has been reviewed and approved by Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or the investigator's responsibilities, you may contact the Manager of Veritas IRB 24 hours per day and 7 days per week at 514-337-0442 or toll free at 1-866-384-4221. An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the subject's rights and welfare in mind. If

you have any study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you need to speak to a person independent from the Investigator and the research staff, and/or if the Investigator and the research staff could not be reached.



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DECLARATION OF CONSENT
Signature Page

I have read the contents of this consent form, and I agree to participate in this research study. I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given sufficient time to consider the above information and to seek advice if I choose to do so. I understand that I will be given a signed copy of this consent form. By signing this consent form, I am not giving up any of my legal rights.

The study doctor has my permission to tell my regular doctor about my being in this study and to relay any pertinent medical information arising from the study that may impact my care:

YES NO

OPTIONS

Future Studies:

The long-term goal of this study is to design and conduct interventional studies that could potentially improve brain health in people living with HIV. We will then be recruiting participants from this cohort who meet the criteria of the interventional studies. Therefore participants in this study may be contacted at a future time and be invited to participate in other studies. At that time you will be asked to sign a new informed consent form.

- I wish to be contacted to participate in other studies
- I **do not** want to be contacted to participate in any other studies

DNA:

Providing a DNA sample is an optional aspect of this study. If you do not wish to participate in this aspect of the study please check the box below. (You will be asked to sign a separate consent)

- I wish to participate in the DNA study
- I **do not** wish to participate in the DNA study

Neurocognitive Assessment:

A random sample of people will be selected to have a full neuropsychological assessment performed, in order to assess their cognition (concentration, memory, attention, problem solving). This will only be done once during the study and take 1.5 - 4 hours. The testing entails the completion of several tasks to evaluate different cognitive functions (thinking, learning, and memory).

This is an optional aspect of the study and if you do not wish to participate please check the box below. You will be asked to sign a separate consent form.

- I wish to participate in the full neuropsychological assessment if selected
- I **do not** wish to participate in a full neuropsychological assessment if selected

Participant's signature Name (in block letters) Date

Signature of Person
Administering Informed Consent Name (in block letters) Date