PARTICIPANT INFORMATION AND CONSENT DOCUMENT

DNA RESEARCH - Optional

Study Title:	Understanding and Optimizing Brain Health in HIV Now
Principal Investigator:	Dr. Réjean Thomas
Study Site:	L'Actuel Medical Clinic
Sponsor:	McGill University Canadian Institute of Health Research (CIHR)

INTRODUCTION

You have agreed to participate in the main study and are now being asked to participate in this DNA sub-study.

Before deciding to participate, you should understand the content of this consent form, the risks and benefits to make an informed decision, and ask questions if there is anything you do not understand. Please read this entire consent form that contains a full explanation of the study and take your time to make a decision. If you decide to participate in this study you will be asked to sign and date this form, and a copy will be given to you.

BACKGROUND

The cells of your body contain deoxyribonucleic acid or DNA for short. The DNA in most cells of your body is the same, and does not change during life. DNA is passed down from parents to their children. It carries the code for the genes that determine your physical appearance such as the color of your hair and eyes. The DNA is specific for an individual, and its code can be determined in the laboratory. Subtle differences in the DNA code of our genes help explain why we all look different. It also can help explain why some people are more likely to get certain diseases, while others do not.

PURPOSE OF THE STUDY

The purpose of this sub-study is to study differences in people's DNA to try to improve our knowledge on how HIV affects brain health. It will help us to evaluate if there is a genetic component to understanding how HIV affects brain health.

STUDY PROCEDURES

You are being asked to provide a single saliva sample that can be stored and used for DNA Research. These tests are not for your medical care. If you agree, a tube of your saliva will be collected at one of the visits of the main study; you won't need to schedule an extra study visit.

STORAGE AND SAFEKEEPING OF DNA SAMPLES

We are seeking your consent to use the DNA from your saliva sample to test genes related to brain health in HIV infected individuals.

If you agree to participate in this study, your DNA will be stored for up to 15 years after the end of the study. The samples will be stored with Montreal Chest Institute, 3650 St. Urbain, Montreal, Quebec.

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

The use of your DNA 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 sample. 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.

POTENTIAL BENEFITS

You should not expect to directly benefit from your participation in this sub-study. However, this research study is part of an effort to collect more information that may provide potential benefit to others in the future.

POTENTIAL RISKS AND DISCOMFORTS

The following information about potential risks is required for any study that involves DNA banking. You will not be exposed to any physical risk associated with the taking of a DNA sample. However, one of the risks associated with this research project relates to the disclosure of the results or the disclosure of your participation to third parties. Unless you have provided specific authorization or where the law permits or a court order has been obtained, your personal results will not be made available to third parties such as employers, governmental organizations, insurance companies or educational institutions. Although unlikely, the fact that potential employers, insurers, or financial institutions could find out about your participation in a genetic research could compromise or diminish your chances and the chances of your family of obtaining insurance (life insurance, disability, mortgage, or health) or certain types of employment. Talk to someone knowledgeable in the implications of genetic testing if you have any questions or concerns.

COST AND COMPENSATION

You will not be paid for participating in this sub-study.

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 (the granting agency, if applicable, depending on the type of research) or the institution of their civil and professional responsibility.

CONFIDENTIALITY

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 L'Actuel 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.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this sub-study is voluntary. You may decide not to agree to this DNA Research study. Whatever your decision, it will not affect your participation in the main clinical study, the usual medical care that you receive from your doctor or your participation in other research studies. You may refuse to participate or discontinue your participation at any time without explanation, and without penalty or loss of benefits to which you are otherwise entitled. Changing your mind about participating in the DNA study will not affect your participation in the main part of the study. If you decide not to participate or if you discontinue your participation, you will suffer no prejudice regarding your medical care. You are free to withdraw from the study at any time. If you withdraw, you may ask for your DNA sample to be destroyed. However, results from tests already done will not be erased. This is to protect the quality of the research. You will be informed of any new findings that may affect your willingness to continue your participation.

FUNDING OF THE RESEARCH PROJECT

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

CONTACT INFORMATION

If you have any questions regarding this research study, contact **Dr. Réjean Thomas** at **(514) 524-1001**.

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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Principal Investigator: **Dr. Réjean Thomas**

Sponsor: **McGill University**
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DECLARATION OF CONSENT FOR DNA RESEARCH

I have read the contents of this consent document and I voluntarily agree that a sample is collected and will be used for DNA research. 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. I will be given a copy of this signed and dated Informed Consent Form. By signing this consent form, I am not waiving any of my legal rights nor am I freeing the investigators, sponsors, or the health establishment where the study takes place from their legal and professional responsibilities.

☐ I freely **agree** that my DNA samples will be stored for future studies

☐ I **do not agree** that my DNA samples will be stored for future studies

Signature of Participant	Name (In block letters)	Date

Person obtaining the informed consent:
I confirm that I have explained the nature and purpose of the DNA Research part of this study and the potential risks and benefits to the subject. The subject indicated whether he/she agreed to participate in the DNA Research study

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