INFORMATION AND CONSENT FORM FOR NEUROPSYCHOLOGICAL EVALUATION

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 are being invited to undergo a neuropsychological evaluation because you have agreed to participate in the main study. You can choose not to participate and it will not affect your participation in the main study.

Please read this consent form carefully. If you decide that you would like to undergo the neuropsychological evaluation, you will be asked to sign this consent form. A copy of the signed and dated consent form will be given to you to keep.

For additional information regarding the study and who to contact with questions or concerns, please refer to main study informed consent form.

BACKGROUND

A neuropsychological evaluation is an assessment of your ability to reason, concentrate, solve problems, or remember.
Two hundred and sixty (260) participants from the Montreal and Vancouver sites will take part in the neuropsychological evaluation.

PURPOSE

The goal of this project is to estimate the sensitivity and specificity of the brief computer-based cognitive assessment, B-CAM (as described in the main study consent) in the diagnosis of cognitive concerns in people living with HIV, when compared against the neuropsychological evaluation, considered as a reference evaluation standard in a number of clinical settings.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation is entirely voluntary. You have the right to refuse to participate in this study. If you decide to participate, your decision is not binding and you may choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services you may receive from this clinic or this hospital. Withdrawal from this sub-study will not affect your participation in the main study.

If you no longer wish to share your personal health information, you may cancel your permission at any time by contacting the study coordinator. 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.

PROCEDURES

This testing will take place at a time that is agreed upon, either during one of the clinic visits or during a separate visit. It will be performed by a professional trained in the administration of these tests. You will be administered a variety of oral and written tests, which will examine your memory (learning and recall), planning abilities, problem solving, language and motor skills.
For some tests, you will be asked to write or draw something and for others you will need to listen and answer questions.You will be given instructions for every task.
The length of testing time depends on your situation and how quickly you work. Testing is usually completed in less than 2 hours.

POTENTIAL BENEFITS AND RISKS

You will not directly benefit from participation in this part of the study. There are no known physical or psychological risks associated with your participation in this study.

RIGHTS AND INDEMNIFICATION IN CASE OF INJURY

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

COMPENSATION

You will not be paid for taking part in this study. However, to cover your travel, childcare, and inconvenience, you will be compensated an amount of $40.00 after completion of the full neuropsychological evaluation.

CONFIDENTIALITY

Your confidentiality will be respected. Your medical information is protected and cannot be used or disclosed without your written consent except as otherwise required by law. However,

research records and health or other source records identifying you may be inspected in the presence of the Investigator or her designate by representatives of the Canadian Institute of Health Research (CIHR) and Veritas Independent Review Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Your primary physician will be made aware of your participation in the study. This is necessary in order to ensure your safety and best medical care.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

Should you wish at any time, now or later, to contact a person who can give you information about 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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DECLARATION OF CONSENT FOR NEUROPSYCHOLOGICAL EVALUATION

I agree to participate in the research study, which has been described to me. I have read and understood the information presented above about the procedures, advantages and disadvantages involved in this study and have received satisfactory answers to my questions related to this study. 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.

With full knowledge of all foregoing I agree, of my own free will, to participate in this study.

☐ I wish to participate in the neuropsychological evaluation
☐ I **do not** wish to participate in the neuropsychological evaluation

_____	_____	_____
Participant's signature	Name (in block letters)	Date
_____	_____	_____
Signature of Person Administering Informed Consent	Name (in block letters)	Date