Centre universitaire de santé McGill
McGill University Health Centre

INFORMATION AND CONSENT FORM FOR COGNITIVE TRAINING SUB-STUDY

Title: **Understanding and Optimizing Brain Health in HIV Now**

Principal Investigators: **Dr. Lesley Fellows & Dr. Marie-Josée Brouillette**

Study Site: **Montreal Chest Institute (MUHC)**

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

INTRODUCTION

You have agreed to participate in the Brain Health Now study and are now being asked to participate in a sub-study on cognitive training.

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

HIV can have subtle but important effects on the brain, leading to difficulties in thinking and concentrating. Computer-based brain training has been shown to improve cognitive abilities (memory, concentration, attention) in some people with brain disorders. However, the effects of such training in people living with HIV are unknown.

PURPOSE OF THIS STUDY

The goal of this project is to determine the extent to which computer-based cognitive training can improve cognitive function in individuals living with HIV who are experiencing difficulties with memory, thinking or concentration. This study will also help us to establish whether people respond differently to the different parts of the training.

STUDY PROCEDURES

If you decide to participate in this sub-study, you will be asked to attend an extra session to review the information given to you at the start of the study of how to improve your brain health. At this information session, you will also be assigned to start the training right away or at a later point in time, after you have worked on achieving a brain health goal.

If you are assigned to start cognitive training right away, you will undergo some additional cognitive testing and will be instructed on how to access the training program from a personal computer. If you are assigned to start the cognitive training later, you will be shown how to use the training program at this later point in time.

The computer-based training will last for eight weeks. It will involve 30-minute sessions, which must be carried-out five times per week. The computer training tasks can be performed anywhere you have access to internet on a computer. The training program is accessible online: you need to go to the study website and log in with the username that you will receive from the investigator (a screen name that contains no personally identifiable information). The training is built as a game where you earn points to advance to the next level and receive continuous feedback on your performance as you engage in cognitive exercises. A trainer will use the secure web portal to regularly check your progress and will provide online or telephone support if needed.

After the eight weeks of training, we will repeat the cognitive tests and ask you a series of questions about your experience with the training program. This should take about 1 hour.
If you were assigned to start the training program at a later point in time, you will still need to come in for the extra information session, undergo the additional cognitive testing (before and after completion of the program) and receive the proper instructions for its use.

Even after the end of the study, and regardless of the group to which you have been assigned, you will be able to keep training on the program as you wish.

POTENTIAL BENEFITS AND RISKS

The benefits of this intervention are unknown. It is however hoped that the information obtained from this study will lead to the development of better tools to access the effects of cognitive difficulties in people living with HIV. There are no known physical or psychological risks associated with your participation in this study.

DISCONTINUATION OF THE STUDY BY THE INVESTIGATOR

The principal clinical investigators and/or the MUHC Research Ethics Board and/or a governmental health department are entitled to terminate the study at any time without your consent. If this is the case, you will be given a full explanation.

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. 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.

COMPENSATION

You will not be paid for taking part in this study. However, you will be compensated for the extra visits related to this substudy. To help you cover your travel, childcare and inconvenience, you will receive $20.00 for the extra information session and $40.00 for the extra cognitive testing session.

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.

CONFIDENTIAL NATURE OF THE STUDY

- The results of the testing will remain confidential in the strict respect of the law. They will be used exclusively for scientific research purposes and will be recorded and maintained in confidence by, and available only to, Dr. de Villers-Sidani and researchers working under his supervision.
- All usage and progress data generated by the training will be encrypted and transmitted to a central server and backed up on a secured local server at McGill. The data will be available for review by Dr. de Villers-Sidani, Dr. Lesley Fellows and Dr. Marie-Josée Brouillette and researchers working under their supervision through a secure web portal. No personally identifiable information, including Internet protocol addresses, will be stored.
- All personal information collected to enroll in the study will be kept separately from the encrypted data and the key-code will be kept securely under lock and in a separate location than the data. Following the collection of results, all data will be kept coded and securely on a local server at the MNI for seven (7) years and will only be available for review by Dr. de Villers-Sidani, Dr. Lesley Fellows and Dr. Marie-Josée Brouillette and researchers working under their supervision. No personal information will be released to third parties without your written approval.
- You should also be aware that the Research Ethics Board or Quality Assurance Officers duly authorized by it may access study data.
- Any secondary use of this data would be restricted to a research protocol in the same or related area of study and would be subject to approval of the Research Ethics Board.
- Should any results be presented or published in scientific journals, you will not be identified by name.

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

FUNDING OF THE RESEARCH PROJECT

The Canadian Institute of Health Research is providing infrastructure support for the conduct of this clinical research and is being run by Dr. de Villers-Sidani, Dr. Lesley Fellows and Dr. Marie-Josée Brouillette. The study doctors are not being paid for including you and looking after you during your participation in this study.

CONTACT INFORMATION

Should you wish at any time, now or later, to contact a person who can give you information about this research study, contact Dr. Étienne de Villers-Sidani at 514 398-8911 or Dr. Marie-Josée Brouillette at 514 843-2090.
In case of emergency during clinic hours (8:00-16:00), contact Dr. Marie-Josée Brouillette at 514 843-2090. After working hours, call 514 934-1934, ext. 33333 and ask for the physician-on-call for the immunodeficiency service.
If you have any questions regarding your rights as a research participant, and you wish to discuss them with someone not conducting the study, contact the McGill University Health Center Ombudsman at (514) 934-1934, ext 35655, who will provide you with independent advice.
You will be emailed a copy of this consent form for your records.

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Principal Investigators: Dr. Lesley Fellows & Dr. Marie-Josée Brouillette

DECLARATION OF CONSENT FOR COGNITIVE TRAINING SUB-STUDY

I agree to participate in the research study, which just 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 cognitive training sub-study if selected
☐ I **do not** wish to participate in the cognitive training sub-study if selected

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