Understanding and Optimizing Brain Health in HIV Now

PARTICIPANT INFORMED CONSENT FORM

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(ask for the Infectious Diseases Physician on call)

INTRODUCTION

You are being invited to participate in this study because you have been infected with Human Immunodeficiency Virus (HIV) for at least a year and you are over the age of 35.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study. By signing this form you give your consent to take part in this study. You will be asked to sign this consent form before any study related procedures take place. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of

benefits to which you are otherwise entitled. Please read this consent form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

This study, conducted by Dr. Marianne Harris, is being sponsored by Canadian Institutes of Health Research (CIHR). Dr. Marianne Harris is being reimbursed by CIHR for the costs of conducting this study.

The UBC Providence Health Care Research Ethics Board (UBC PHC REB) has reviewed and approved this research. The UBC PHC REB is tasked with ensuring that research is conducted in an ethically acceptable and scientifically sound manner and aims to help protect the rights of research subjects.

BACKGROUND

In Canada, the effects of 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 may affect brain health. Eligible participants who agree to be in the study will be assessed at an initial study (baseline) visit, then at 9 months, 18 months, and 27 months (for a total of 4 visits over 2 years and 3 months). At each study visit, mood will be assessed by answering a set of questions (described in more detail later in this document). Previous studies in people without HIV have shown that depression can occur several years before problems with cognition. This study aims to determine whether, in people living with HIV, depression can occur before or after the start of problems with cognition, or if these conditions can develop at the same time. This will help us understand how difficulties with mood and cognition develop over time and their impact on daily living among people living with HIV.

Eligible participants who are found to have problems with cognition at any time during the study will be invited to participate in one or more optional sub-studies, to investigate different strategies to improve brain function in individuals living with HIV. Potential participants will be provided with a separate informed consent document that describes the details of these sub-studies before deciding whether to take part in it.

PURPOSE OF THE STUDY

The purpose of this study is to understand how the 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. The St. Paul's Hospital site will enroll up to 200 participants.

WHO CAN PARTICIPATE IN THIS STUDY

You may be eligible to participate in this study if:

- you are 35 years or older
- you have had HIV infection for at least 1 year

WHO SHOULD NOT PARTICIPATE IN THIS STUDY

You will not be eligible to participate in this Study if you have any of the following:

- dementia (a serious impairment in cognition, like Alzheimer's disease)
- an infection (other than HIV) related to the brain or spinal cord (for example, meningitis or toxoplasmosis)
- hepatitis C requiring treatment with interferon during the follow-up period
- psychotic disorder or disease (serious psychiatric illness, such as schizophrenia)
- substance or alcohol dependence now or within the past 12 months.

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.

During your first visit, 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.

At each visit the study coordinator will perform the following assessments:

	Assessment	Details	Purpose	Time
	Brief assessment of Cognition	a computer-based program with the help of the study coordinator.	Assess your memory, concentration, attention	30-45mins
	Research Samples	-30 mL (6 tsp) of blood will be drawn at the same time as your routine blood tests. You will be required to fast (nothing to eat or drink, except water) for at least 8 hours prior to the blood test	Storage for future research related to HIV and cognition	5mins
	Questions about your health, medications, and a limited physical examination	Study coordinator will ask you some questions and measure your weight, height, blood pressure, waist and hip circumference	Evaluate the current state of your health	5mins
	Questionnaire	Series of questions to be answered by you (details below)	To assess your overall health and quality of life	About 2 hours

As noted in the table above, at each visit you will be asked to answer a questionnaire about your overall health and quality of life (including questions about your education and work; smoking, alcohol and drug use; HIV symptoms; depression, anxiety, and stress; physical activity; and relationships with friends and family). You do not have to answer any questions which make you feel uncomfortable.

Since the questionnaire takes about 2 hours to complete each time, you will be given several options to complete it. These include completing it 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 study coordinator, at a time that has been agreed upon. It is important that no other person answers any of the questions 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 questionnaire.

In addition, at one study visit , chosen at random by the study sponsor, a urine sample will be collected and tested for the presence of street drugs. This result will be compared with your responses to questions about your use of street drugs. These results will not be shared with any parties not directly involved in the study.

Also, you will be requested to provide a saliva sample for genetic (DNA) testing during a single study visit. This part of the test is optional, and you can still participate in the main study if you chose not to provide the saliva sample. You will be provided with a separate consent form that describes this part of the study in more detail.

The total time required for study participants will be about 12-16 hours over 2 years and 3 months. The total amount of blood which will be collected from you throughout the study up to 2 years and 3 months will be approximately 120 mL (about half of one cup). A standard blood donation is about 500 mL (about 2 cups).

Some study participants (260 for the entire study and about 85 at the St. Paul's Hospital site), chosen at random, will be asked to have a full cognitive evaluation during a single separate session during the study. This is longer and more complete than the brief 30-minute assessment of cognition performed at each study visit. This in-depth 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. You will not receive the results or feedback from this testing; it is being done only for research purposes. This additional testing is optional and you will be asked whether you agree to this additional testing at the end of this document. If you do not wish to have this testing done, you can still continue to participate in the main part of the study.

We 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.

POTENTIAL RISKS OR DISCOMFORTS:

You will be asked questions regarding your mood and brain health. It is possible but unlikely the questionnaires could result in emotional distress. If you have having

difficulties with your emotions (e.g. feeling depressed or anxious) and would like help managing those difficulties, the study staff can arrange for you to see a counsellor in the Immunodeficiency Clinic; however, any costs associated with such counselling will not be covered by the study.

We will take every possible precaution to ensure that the results of these tests will be kept confidential; there is minimal risk of your test results being accidentally sent to a third party.

Blood Draws

Risks associated with blood drawing (1%) include pain, bruising, bleeding or other discomfort at the blood drawing site. Rarely, anemia, fainting or infection at blood drawing site may occur. Precautions will be taken to minimize these difficulties.

POTENTIAL BENEFITS

Participants may not directly benefit from participation in this study. 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, 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.

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

RIGHTS AND COMPENSATION

By signing this form, you do not give up any of your legal rights and you do not release the study doctor or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any research procedures.

You will not be reimbursed for your participation in this study. However, you will be compensated for your travel expenses 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.

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. Decision to withdraw can be made verbally or in writing. If you change your mind about your participation and do not want your biological samples to be used for research, you should inform the study staff. In this case, your sample will be removed from storage and destroyed by incineration by a company specialized in the elimination of biological samples. Clinical data collected will be conserved but any link to your personal information (names, address etc.) will be permanently deleted.

STORAGE AND SAFEKEEPING OF BLOOD AND DNA SAMPLES

As part of this study, we will be collecting and storing blood samples in order to conduct future research related to HIV and cognition.

If you agree to participate in this study, your 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. 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.

Should additional testing be required on your samples, the research team would seek written approval from the PHC Research Ethics 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

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 the UBC/PHC Research Ethics 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. 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.

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.

NEW FINDINGS

You will be informed of any important new information discovered during the course of the study, which may affect your willingness to continue taking part in this study.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions during the study, or if you experience any side effect or research related injury, please contact Dr. Marianne Harris or members of her research staff at 604-806-8771 during the day and the Infectious Diseases Physician on call at 604-682-2344 after hours.

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

Note: Please keep a copy of this Consent Form for your information throughout the study. Once you have signed the Consent Form, your Study Doctor will give you a copy for your own reference.

OPTIONS

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

Future Studies:

The long-term goal of this study is to design and conduct studies looking at treatments (for example, brain exercises) that might improve brain health in people living with HIV. We will be inviting eligible participants in the present study to participate in one or more of such treatment studies.. Therefore, if you agree, we may wish to contact you at a future time and invite you to participate in other studies. At that time you will be asked to sign a new informed consent form giving you information about the new study.

☐ I wish to be contacted about possible participation in other studies
☐ I do not want to be contacted about possible participation in other studies

Full Cognitive Assessment:

Some study participants will be chosen at random to have a full cognitive assessment performed, in order to assess their concentration, memory, attention, and problem solving in more detail. This will only be done once during the study and will take one and a half to four hours. The testing involves several tasks to test different aspects of thinking, learning, and memory. If you agree to this testing and are selected, you will be provided further details and an appointment will be scheduled at your convenience.

This is an optional part of the study. You may choose not to participate and still take part in the main study.

☐ I agree to participate in the full cognitive assessment
☐ I do not wish to participate in a full cognitive assessment

PARTICIPANT CONSENT AND SIGNATURE PAGE

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- I have received an explanation of the nature, purpose, duration and foreseeable effects of the study and what I will be expected to do. The possible risks and benefits of the study have been explained to me.
- I was given time and opportunity to inquire about the study and all my questions were answered to my satisfaction.
- I agree to fully co-operate with the study doctor and research staff
- I am free to withdraw from the study at any time, without the need to justify my decision and without any disadvantage to my further medical treatment.
- I agree that results of the study may be passed on to the granting agency (CIHR) under investigation. Any information that identifies me will be kept confidential.
- I agree that by signing this consent form, I give permission to release information regarding my participation in this study to the service provider where data will be hosted (Dacima Software, 8600 Boulevard Décarie #201, Montréal, QC H4P 2N2).
- I understand that representatives of the Research Ethics Board or the granting agency (CIHR) may wish to inspect my medical records in the presence of the investigator, to verify the information collected. By signing this document I give permission for this review of my records.
- I understand that I do not give up any legal rights.
- I have read this consent form and I agree to take part in this research study.
- I have been told I will receive a copy of this signed and dated consent form.

Signature of Participant	Name (please print)	Date
Signature of Person Conducting Informed Consent Discussion	Name (please print)	Date
Signature of Principal Investigator/Designate	Name (please print)	Date