Understanding and Optimizing Brain Health in HIV Now

OPTIONAL DNA RESEARCH

PARTICIPANT INFORMED CONSENT FORM

Principal Investigator:	**Dr. Marianne Harris**	**604-806-8771**
Co-Investigators:	**Dr. Mark Hull** **Dr. Julio Montaner** **Dr. Silvia Guillemi**	
	24 hour telephone number **(ask for the Infectious Diseases Physician on call)**	**604-682-2344**

You are being invited to participate in this optional part of the study because you have agreed to participate in the main study. All participants in the main study will be asked to take part in this optional part of the study. You can choose not to participate in the sub-study and it will not affect your participation in the main study.

Please read this consent form carefully. This form explains the things you will be asked to do before, during, and after the study. If you decide that you would like to take part in this study, 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

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.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this portion of the study is voluntary. That means that you can decide not to take part. If you agree to take part, you can change your mind at any time for any reason without losing any benefits to which you would have received if you were not in the study. You can continue to take part in the main research study whether or not you choose to take part in this optional portion of this study. You may withdraw your consent to take part in this portion of the study at any time by any means. Your decision not to take part, or to withdraw from participation, will not affect the medical care, education, or other services that you may receive from this clinic or this hospital. 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.

PROCEDURES

You are being asked to provide a single saliva sample that can be stored and used for DNA Research. You will be asked to spit a small amount (2mL or about half a teaspoon) of saliva into a plastic tube containing a solution which protects DNA from breaking down. This test is 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, in the future, search for variations in the genes known to be related to mood and cognition 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 the PHC Research Ethics Board 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 RISKS OR 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.

POTENTIAL BENEFITS

You will not receive any direct benefit as a result of your participation in this additional research. However, the knowledge gained may help others in the future.

RIGHTS AND COMPENSATION

There will be no cost to you for participating in this optional portion of the study. You will not be paid for taking part in this optional portion of the study.

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 and/or by the study sponsor (CIHR).

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.

PARTICIPANT CONSENT AND SIGNATURE PAGE

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Optional DNA Research

- 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 and Title (please print)	Date
Signature of Principal Investigator/ Co-investigator	Name (please print)	Date