BRITISH COLUMBIA CENTRE *for* EXCELLENCE *in* HIV/AIDS

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Providence HEALTH CARE
How you want to be treated.

Evaluation of health inequities among HIV positive and HCV co-infected men and women and the impact of these inequities on the implementation of Seek and Treat to Optimize Prevention of AIDS (STOP-AIDS) Program

Participant Informed Consent Form

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24 hour telephone number 604-682-2344
(Ask for the Infectious Diseases Physician on call)

This consent form may contain words that you do not understand. Please ask the study coordinator or any member of the study team to explain any words or information that you do not understand. You can contact the study team at 1-855-506-8615, option 2 or shape@cfenet.ubc.ca

INTRODUCTION
You are being invited to participate in this study that aims to find out more about your experiences using HIV health care and how this impacts your long-term health.

By signing this form, verbally giving your consent over the phone or clicking "Agree and Continue" on our website, you give your permission to take part in this study. More information on how to provide consent is included in the "Study Procedures" section of this consent form. Please read this consent form and ask the study team as many questions as needed. You should not provide your consent to participate in this study if you have any questions that have not been answered to your satisfaction.

This study, conducted by Dr. Rolando Barrios, is being sponsored by the BC Centre for Excellence in HIV/AIDS (BC CfE) and the BC Ministry of Health. This study has been approved by the UBC/Providence Health Care Research Ethics Board at St. Paul's Hospital.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation is entirely voluntary. You have the right to refuse to participate in this study. You should take part in the study only if you want to do so**.** If you decide to participate, 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. If you do decide to withdraw from the study, we will not use any collected data or survey information concerning you.

PURPOSE OF THE STUDY
The purpose of this study is to understand what factors help individuals to access HIV testing, care and antiretroviral therapy in a time of increased funding for HIV health care through the STOP HIV/AIDS Program.

WHO CAN/ CANNOT PARTICIPATE
You are eligible to participate in this study if you:

- Have been diagnosed as HIV positive;
- Are at least 19 years old;
- Live in BC during the study period;
- Can complete and feel comfortable completing the survey in English;
- Are able to provide informed consent; and,
- Meet our recruitment targets*.

*To make sure we are getting a representative sample of individuals living with HIV in British Columbia in this study, we have established maximum allowable numbers for how many people can do the survey with certain characteristics. For example, out of our total possible study population of 810 people, a maximum of 315 people can be aged 50 and over at the time they do the survey to make sure that people in other age groups are able to participate as well.

STUDY PROCEDURES

Before we collect any information about you, including whether you meet our recruitment targets to see if you are eligible, we need your consent to participate. You can show your consent by either signing the last page of this consent form and returning it to the study coordinator, or by giving your verbal consent to participate over the phone, or clicking 'Agree and Continue' online to start the registration questions. Please see the last page of this form for information on how to return this form to the study coordinator.

If you are eligible to participate and agree to participate in this study, it will involve filling out a baseline survey and two follow-up surveys 18 months apart after you complete the previous survey. There are a few options for how the surveys can be completed. You may complete the surveys online by yourself, or a trained interviewer can guide you through the surveys either in person at St. Paul's Hospital in Vancouver or over the phone using our toll-free phone number. The surveys will take approximately 45 to 75 minutes to complete.

The surveys include questions about your gender, ethnicity, place of birth, and sexual orientation. These are very personal questions and providing this information is entirely voluntary. The reason we ask these personal questions is because there are certain people who are especially vulnerable to poor HIV-related health outcomes and we want to better understand why. You do not have to answer any questions in the surveys that make you feel uncomfortable.

Our priority is the comfort, safety and security of all of the participants in this study. We have professional obligations to come to the aid of persons who are at immediate risk of harm to themselves as well as professional and legal obligations to prevent harm to others. If you let us know that you have suicidal feelings or thoughts of harming others during the survey, interviewers are compelled by legislation to report this to the appropriate agency or authority. This mandatory process is in place to make sure you and others are kept safe. If you are completing the survey online by yourself and feel troubled by the content of the survey, please see the "Potential Risks or Discomforts" section of this consent form for the contact information for the Crisis Intervention & Suicide Prevention Centre of BC.

FOLLOW-UP

You will be contacted at a later date to invite you to complete the two follow-up surveys, using the contact information that you will be asked to provide before you start the survey. The research team may also contact you for further clarification, missing information regarding your survey responses or if the survey was only partly finished. For example, if a question was skipped when you did the survey we may ask you to provide the missing information. If you do not wish to provide the missing information you will not be pressured to do so.

POTENTIAL RISKS OR DISCOMFORTS:

There may be topics that arise during the surveys that deal with sensitive and personal issues such as experiences of violence, relationships and/or HIV-status. The interviewers leading the surveys are trained and will be well-equipped to handle minor situations

and/or refer the in-person and telephone participants to centres of care that are more suitable to provide further care to the participant. If you are completing the survey on your own online and feel distressed, please contact the Crisis Intervention & Suicide Prevention Centre of BC to speak to someone who can help: 604-872-3311 or toll free 1-866-661-3311.

Loss of confidentiality is a potential risk of participating in this study. There are several mechanisms in place to ensure the confidentiality of all participants. Refer to the section on "Confidentiality Procedures and Data Storage" in this consent form for more information.

POTENTIAL BENEFITS

You are not guaranteed to receive any benefit from participating in the study. It is possible that you may get better, stay the same, or get worse. Participating in this study may help other patients with HIV infection by leading to the development of improvements to health services.

RIGHTS AND COMPENSATION

By agreeing to this form, you in no way give up any of your rights and you do not release the study doctors or other participating institutions from their legal and professional responsibilities. You may stop and/or quit your participation at any time, without reason.

There will be no costs to you for participation in this study. You will not be charged for any research procedures.

You will be provided with a $30 honorarium for completing this survey. You will be provided with an additional $30 cash honorarium for each of the two follow-up surveys. The honoraria will be paid by cheque or cash, depending on what works best for you. The honoraria will be mailed to you if you complete the survey online or over the phone, and will be given to you at the end of the survey if you complete it in person.

DATA LINKAGES

Your survey information may be linked to your clinical data and to health-related data held by the BC Ministry of Health. This may include information such as CD4 count, viral load, and use of antiretroviral medications from the BC CfE and laboratory, physician and hospital services and vital statistics from data held in the Medical Services Plan, Hospital Discharge, Pharmacare/net and Vital Statistics Registries held by the BC Ministry of Health. These data linkages are important for us to further understand your clinical and health service history related to HIV/AIDS. Your identity will be kept strictly confidential and the final dataset will not include any personal identifying information about you.

CONFIDENTIALITY PRCOEDURES AND DATA STORAGE

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the study's Principal Investigator, or his or her designate, by representatives of the BC CfE, and the University of British Columbia 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.

As part of participating in this study, you will be asked to provide three pieces of identifying information: 1) your Personal Health Number (PHN) 2) your full name, and 3) your date of birth, so we can link your survey responses to your clinical data (as described in the Data Linkages section of this document). This information will be protected under the strictest provincial and federal privacy and confidentiality standards.

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. 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.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the study and, if need be, an opportunity to correct any errors in this information. If you would like further details about these laws, please contact the research ethics board via the Research Participant Complaint Line using the number listed in the next section of this form.

All signed consent forms (for people who complete the survey in-person with an interviewer) will be kept in a secure area in locked cabinets at the BC-CfE and electronic data will be stored on a secure server located at the BC CfE. Study documents will be kept for 5 years, at which time they will be destroyed. Consent forms will be shredded and electronic data will be deleted.

For individuals who complete the registration process of this study but are not eligible to participate in the survey, any information entered online in the participant registration webpage will be automatically deleted once the 'Exit study' button is clicked on the registration results page or once the internet browser tab is closed.

For individuals who begin the survey and are unable to complete it fully at that time, you will be able to log back in to the survey within 7 days of when you first started to survey to complete it. You can log back in using the "Existing Participant" tab on the SHAPE study website and entering your PHN, name and date of birth to confirm your identity. After 7 days, surveys that are not completed will be deleted from our database because we can only include completed surveys in our study. Only individuals who complete the survey will receive the honorarium for participating.

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. Rolando Barrios or the Project Coordinator at 1-855-506-8615, option 2, during the day and the Infectious Diseases Physician on call at 604-682-2344 after hours. The research team is conducting this research under the authority of the University of British Columbia/Providence Health Care.

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

If you are completing the survey from within Interior Health Authority, you may also contact the Chair of the Interior Health Research Ethics Board by phone at 250-870-4602 or via email to researchethics@interiorhealth.ca

IF COMPLETING THE SURVEY OVER THE PHONE OR IN PERSON, PLEASE SIGN BELOW AND DETACH THIS PAGE FROM THE REST OF THE CONSENT FORM AND SEND EITHER:

A) Via mail to: SHAPE Study, BC Centre for Excellence in HIV/AIDS, St. Paul's Hospital, 608-1081 Burrard Street, Vancouver, BC, V6Z 1Y6
B) Scan and send via e-mail to shape@cfenet.ubc.ca

If neither of these options work for you, let us know and we will ask for your verbal (for phone interviews) or written (for in-person interviews) consent to participate before we start the survey with you.

PARTICIPANT CONSENT AND SIGNATURE PAGE

- I have read this consent form and I agree to take part in this research study.
- I have been offered a copy of this consent form.
- 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 that any information that identifies me will be kept confidential.
- I understand that representatives of the sponsor, the BC Ministry of Health, the Research Ethics Board or regulatory authorities 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, if necessary.
- I understand that any questions I may have can be addressed at any time to the research team.
- I understand that the research team must receive my consent to participate before any information is collected.
- I am free to withdraw from the study at any time, without justification or reason and without any disadvantage to any medical treatment or support I may be receiving or may receive in the future.

Signature of Participant	Name	Date

FOLLOW UP:

□ I consent to being contacted by the research team for purposes of completing the two follow-up surveys

□ I do not want to be contacted by the research team for any reason following this baseline survey