The SHAPE Study

(Full title: 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 for Follow-up Survey #1

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St. Paul's Hospital
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.

INTRODUCTION
You are being contacted to complete a follow-up survey for the SHAPE study. This study 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. 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 should take part in the study only if you want to do so**.** You may choose to withdraw from the study at any time without any negative consequences to the medical care, 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.

STUDY PROCEDURES
Before we collect any information about you, we need your consent to participate in the follow-up survey. You have already consented to participate in this study, but because of the long time between the baseline and follow-up survey we are required to ask for your consent again. Everything that you already committed to in the original consent form still applies. You can show your consent by either signing the last page of this consent form and returning it via email to the study coordinator, or by giving your verbal consent to participate in the follow-up survey over the phone, or by clicking 'Agree and Continue' online. Please see the last page of this form for information on how to return this form to the study coordinator, if needed.

As with the baseline 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 (1-855-506-8615, option 2). The surveys will take approximately 45 to 75 minutes to complete.

The SHAPE follow-up 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. We will also ask you COVID-19 related questions, such as, questions about your ability to access care during the COVID-19 pandemic restrictions. 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 a second follow-up survey, using the contact information that you will be asked to provide before you start the follow-up survey. The research team may also contact you to participate in a further qualitative interview, 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. For follow-up surveys completed over the phone, the study coordinator or study team member will conduct the phone call from a private office over an office phone. 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. 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. 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.

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 electronic consent forms and data will be stored on a secure server located at the BC CfE. Study documents, including consent form signature pages, and data will be kept for 5 years in a secure area in locked cabinets at the BC-CfE. After 5 years all study documents will be destroyed. Electronic consent and electronic data will be deleted.

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 the 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 ONLINE, BY CLICKING 'AGREE AND CONTINUE' ON THE STUDY WEBPAGE YOU ARE PROVIDING YOUR CONSENT TO PARTICIPATE AND BE CONTACTED FOR THE FOLLOW-UP INTERVIEWS

PARTICIPANT CONSENT

Clicking "Agree and Continue" means:

- I have read this consent form and I agree to take part in this research study.
- I agree to be contacted by the study team at a later date to complete the second follow-up survey, regarding missing information in the survey or regarding a potential qualitative interview.
- I have been offered a copy of this consent form.
- I have understand the nature, purpose, duration and foreseeable effects of the study and what I will be expected to do.
- I was given time and opportunity to inquire about the study and all my questions were answered to my satisfaction.
- I understand 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.