



The STOP HIV/AIDS Program Evaluation (SHAPE) Study 2.0

Participant Informed Consent

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INVITATION AND PURPOSE OF THE STUDY

You are being invited to participate in the STOP HIV/AIDS Program Evaluation (SHAPE) study. This study aims to find out more about the experiences of persons living with HIV (PLWH) in British Columbia (BC) using HIV health care services and to identify unmet health service needs. Up to 4000 participants will be enrolled in this study across BC.

It is up to you to decide whether or not you want to take part in this study. It is completely voluntary. By taking part in this study, you do not give up any legal rights. If you do not want to take part in this study, it will not affect your medical care treatment or access to supportive services and programs at your various clinics or elsewhere. You also will not be denied the opportunity to take part in other studies conducted by the BC Centre for Excellence in HIV/AIDS. Even if you agree to take part now, you can change your mind later. You do not have to give us a reason why. In that case, we will destroy all of your study files.

WHO CAN PARTICIPATE IN THIS STUDY?

You are eligible to participate in this study if:

- You are HIV positive
- You are at least 19 years old
- You are currently residing in BC and enrolled in the Drug Treatment Program (DTP)
- You are able to complete the survey in English
- You are willing and able to provide informed consent

STUDY PROCEDURES

We will confirm eligibility through the BC Centre for Excellence in HIV/AIDS (BC-CfE) HIV Drug Treatment Program (DTP) registry, which will require your name, personal health number (PHN) and/or date of birth.

If you are eligible and consent to participate in the SHAPE study, you will be asked to fill out one survey. The survey will take approximately 30 minutes to complete. There are different options available to complete the survey. You may complete the survey by yourself online, or with a trained interviewer who can guide you through the survey either in person at St. Paul's Hospital or the Hope to Health clinic in Vancouver or other locations across BC, or over the phone using our toll-free phone number (1-855-506-8615).

If you wish to participate in the study online, you will be required to go through the consent web page of the survey to provide your consent electronically. A check box will be available for you to choose whether you accept or refuse to participate. Should you accept to participate, you will provide your signature and date. After consenting to participate then you can proceed

to the screening questions. If you are participating in person or by telephone, an interviewer will explain the study to you and request for your verbal consent.

The survey includes questions about your gender, ethnicity, place of birth, and sexual orientation. Examples of questions you may be asked in the survey are: “What term best describes your gender?” “What ethnic group or family background do you identify with?” 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 would like to understand why. Please keep in mind, you do not have to answer any questions in the surveys that might make you feel uncomfortable. You are also welcome to stop participating at any time. However, you will receive the full honorarium, regardless of completeness.

DATA LINKAGES

To better understand your medical history and your use of health services related to HIV/AIDS, we will need your permission to link the data from the survey you will complete for this study to your information held in the BC-CfE DTP registry database. The DTP database includes data such as your CD4 count, viral load, and your use of antiretroviral medications. We also require your permission to access your administrative health records held by the BC Ministry of Health. These data linkages are important for us to achieve the study objectives.

By consenting to this form, you agree to the BC Ministry of Health and the BC-CfE DTP transmitting these data to the researchers. These data linkages may provide additional identifiable information about you. Therefore, for all data linkages, your name, date of birth, and Personal Health Number will be used solely to locate information about you in other records and only a unique study number (e.g., xb100000009) will be assigned to those identifying information.

These linkages will remain active to prospectively monitor key outcomes from the study, and linkages to administrative data will be updated periodically. The merged data will be securely stored and accessed only as outlined in this consent form.

POTENTIAL RISKS OR DISCOMFORTS:

Some of the topics in the survey deal with sensitive and personal issues such as experiences of violence, relationships and/or HIV status. If you feel in distress and need support when completing the survey, and you would like to speak to someone about how you are feeling, the interviewer leading the survey is trained to handle minor situations and/or refer you to centres of care more suitable to provide you with further support. 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 1-800-784-2433.

POTENTIAL BENEFITS OF THE STUDY

We do not think taking part in this study will help you. However, in the future, others may benefit from what we learn in this study.

COMPENSATION

There will be no costs to you for participation in this study. You will receive \$40 after you finish the survey to compensate you for your time. If you chose not to answer some questions, you will still receive the full amount after completing the survey. The \$40 will be paid by electronic transfer, cheque or cash depending on what works best for you. The \$40 can be given to you in cash or transferred to you electronically if you complete the survey in person, online, or over the phone. If you do not have an email address and you complete the survey online or by telephone, a cheque will be mailed to you after completing the survey.

CONFIDENTIALITY

Your confidentiality will be respected. As part of participating in this research, you will be asked to provide your full name on the signature page of this consent form. You will be assigned a unique study number. 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 Investigators and/or other authorized staff. Information that discloses your identity will not be 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.

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 containing consent forms 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 containing consent forms will be deleted.

If you 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.

If you begin the survey and are unable to complete it fully at that time, you will be able to log back in to the survey using the “Continue the Survey” button on the SHAPE study website and entering your PHN, name and date of birth to confirm your identity.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions or concerns about what we are asking of you, please contact the SHAPE study team at 1-855-506-8615 or email shape@bccfe.ca.

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). Please reference the study number H23-03366 when calling so the Complaint Line staff can better assist you.

STUDY RESULTS

The main study findings will be published in academic journal articles. Study findings and publications will be available on the BC Centre for Excellence in HIV/AIDS website (www.bccfe.ca). Only your de-identified data, pooled with the data from other participants, will be shared in public repositories that promote open access publishing. Open access is a set of principles that promote the sharing of research data and outcomes openly for the research community and the public, to advance knowledge. We also plan on bringing our findings back to community organizations through carrying out various presentations, posters and infographics.

The STOP HIV/AIDS Program Evaluation (SHAPE) 2.0 Study

IN-PERSON PARTICIPANT CONSENT

- Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your medical care.
- Your signature below indicates that you have received a copy of this consent form for your own records.
- Your signature indicates that you consent to participate in the SHAPE 2.0 study.

Full Name of Participant

Date

The STOP HIV/AIDS Program Evaluation (SHAPE) 2.0 Study

PARTICIPANT VERBAL CONSENT

- I agree to participate in the SHAPE 2.0 study:

YES NO

Verbal consent to participate in this study was given by:

Full Name of Participant

Full Name of Participant Person
Conducting Verbal Informed Consent
Discussion

Date

The STOP HIV/AIDS Program Evaluation (SHAPE) 2.0 Study

ONLINE PARTICIPANT CONSENT

- Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your medical care.
- By checking agree and providing your signature below, you consent to participate in this study.
- I agree to participate in the SHAPE 2.0 study:

Agree Disagree

Full Name of Participant

Date