Semaglutide (Ozempic®, Wegovy®, and Rybelsus®) and ALcohol: a Self-reported Assessment (SALSA) Study in two Clinical Populations in Vancouver, British Columbia, Canada

Participant Informed Consent

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BC Centre for Excellence in HIV/AIDS

NOTE: If you are participating online the submission of the survey confirms your consent to participate in the study.

INVITATION AND PURPOSE OF THE STUDY

You are being invited to participate in the Semaglutide (Ozempic®, Wegovy®, and Rybelsus®) and ALcohol: A Self-Reported Assessment (SALSA) study. The SALSA study aims to assess the impact of semaglutide (Ozempic®, Wegovy®, and Rybelsus®) on self-reported alcohol consumption and weight among individuals with type 2 diabetes, obesity, and/or metabolic syndrome, including those living with or without HIV, in two outpatient clinics. Up to 100 participants will be enrolled in this study.

It is up to you to decide whether or not you want to take part in the SALSA 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 the SALSA study if you:

- Are aged 19 years or older
- have been prescribed semaglutide for the management of type 2 diabetes or for weight loss
- have received your initial prescription for semaglutide treatment by your physician.
- have at least six months of follow-up since starting semaglutide treatment
- Are willing and able to provide informed consent for study participation
- Are able to complete the survey in English

You are unable to participate in the SALSA study if you:

- are unable to complete the survey in English
- are pregnant or have other contraindications for semaglutide
- are taking any of the following drugs for any reason:
    - Disulfiram (Antabuse),
    - naltrexone (Revia, Vivitrol),
    - acamprosate (Campral),
    - topiramate (Topamax),
    - gabapentin (Neurontin)

STUDY PROCEDURES

If you are interested in participating in the study, you will be required to go through the consent web page prior to proceeding to the screening questions. The screening questions are to confirm if you are eligible to participate in the study. You will be asked whether you have been taking Ozempic®, Wegovy®, or Rybelsus® (a Semaglutide) for at least six months, your age, whether you are pregnant and if you are taking any of the medications listed above that would make you unable to participate in the study.

In order for us to verify your eligibility, we will need to confirm your medication history within your Pharmanet record. To access your Pharmanet record, we will require your full name, date of birth, and your personal health number (PHN).

You will also be asked to provide a phone number or email address where you can be contacted. A member of the study team will verify that you are eligible to participate based on your medication records and contact you based on your preferred method of contact.

If you are not eligible to participate in the study, you will be contacted by the study coordinator to confirm that any information you provided will be deleted.

If you are eligible and consent to participate in the study, you will be contacted by the study coordinator and provided with a link to fill out the 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 at St. Paul's Hospital, or over the phone.

Submission of the survey online confirms your consent to participate in the study. If you are participating in person, an interviewer will explain the study to you. If you are participating by telephone, an interviewer will explain the study to you over the phone and will request your verbal consent prior to commencing the survey with you over the telephone.

The survey includes questions about your sex, ethnicity, and sexual orientation. Examples of questions you may be asked in the survey are: "what is your sex assigned at birth?" **"**In our society, people are often described by their cultural background. These are not based in science, but our cultural background may influence the way we are treated by individuals and institutions, and this may affect our health. What term best describes your cultural background?" 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 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.

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 $30 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 $30 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, please

contact our team by calling 604-806-8477 ext. 66272 or emailing salsa@bccfe.ca to determine an alternate method of payment.

CONFIDENTIALITY

Your confidentiality will be respected. As part of participating in this research, you will be asked to provide your full name, date of birth, and personal health number (PHN). Your PHN will be used to verify that you have been taking Ozempic®, Wegovy®, or Rybelsus® for at least six months, and that you are not taking any of medications that would exclude you from being eligible for participating in this study. 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 name 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. 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. 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 eligibility screening webpage will be automatically deleted once the 'Exit study' button is clicked on the eligibility screening 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 SALSA study website and entering your last name and the 4 digit access code which we will provide you.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions or concerns about the study, a study team member is available to discuss the consent form and study with you. Please call at 604-806-8477 ext. 66272 or email salsa@bccfe.ca to set up a time for the research coordinator to discuss the study with you and answer any questions you might have.

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 **REB# H25-00654** when calling so the Complaint Line staff can better assist you.

STUDY RESULTS

The main study findings will be published in academic journal articles or presented at conferences. 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.

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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, and having your medication history accessed to confirm your eligibility to participate in this study.

- I agree to participate in the SALSA study:

  ☐ Yes ☐ No

- I agree to the study team accessing my medication history to confirm my eligibility to participate in this study.

  ☐ Yes ☐ No

INTERVIEWER-ADMINISTERED VERBAL 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 SALSA study:

  ☐ YES ☐ NO

Full name of person conducting verbal informed consent discussion: _____

Date: _____