THE MOMENTUM HEALTH STUDY

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CONSENT FORM FOR SURVEY PARTICIPANTS

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

UBC

University of Victoria

This Consent Form may contain words you do not understand. Please ask the study staff to explain any words or procedures that you do not clearly understand.

Momentum Health Study Phase III: "Uptake and effectiveness of post-exposure prophylaxis using doxycycline to prevent bacterial sexually transmitted infections among gay, bisexual and other men who have sex with men in Vancouver, BC"

PRINCIPAL INVESTIGATORS

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This study is funded by the Canadian Institutes of Health Research

INTRODUCTION

You are being invited to take part in this research study because you identify as a man and have had sex with other men in the previous six months.

VOLUNTARY PARTICIPATION

Your participation in the study is completely voluntary. You may refuse to take part or withdraw from the study at any time, and without giving any reason for your decision. Please note, we will retain any information contributed to the study up to the point of withdrawal from the study.

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Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

You should not sign this form if the study staff has not answered your questions to your satisfaction.

Who is Conducting this study?
This study is sponsored by operating grants from the Canadian Institutes of Health Research The research is being led by Dr. David Moore of University of British Columbia and the B.C Centre for Excellence in HIV/AIDS Research and Dr. Nathan Lachowsky of the University of Victoria

BACKGROUND
Gay, bisexual, and other men who have sex with men (GBM) are more affected by HIV and other sexually transmitted infections (STIs) than other groups in Canada. Although the number of HIV cases in GBM has gone down in recent years, they still have the highest number of new HIV cases in Canada compared to other groups. On the other hand, cases of bacterial STIs like syphilis, gonorrhea, and chlamydia have been rising for both men and women over the past 10 years. Recently, the antibiotic doxycycline has been tested as a way to prevent bacterial STIs before or after exposure and has been shown to help reduce STIs in GBM.

PURPOSE OF THIS SURVEY
We want to learn more about how gay, bisexual, and other men who have sex with men (GBM) in Metro Vancouver react to new treatments that help prevent HIV and other sexually transmitted infections (STIs), and how their risk behaviors change over time. We also want to understand how their thoughts, feelings, and actions around sexual health, mental health, and recreational drug use change. We are very interested in how the new use of the antibiotic doxycycline to prevent STIs in BC is affecting how GBM live, love, and have fun.

ELIGIBILITY
You may be able to participate in this study if you:

1. Identify as a man
2. Are 16 years of age or older
3. Report sexual activity with a man in the previous six months
4. Receive a RDS voucher for participation in the study, or be purposively invited as an initial "seed" recruit
5. Reside in Metro Vancouver and surrounding areas

You will not be able to participate in this study if you:

1. Cannot complete a computer-based survey in English
2. Are not 16 years of age or older

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STUDY PROCEDURES

This study will enroll a target of 720 GBM in Vancouver. Simultaneously, target samples of 720 GBM will be enrolled in Toronto and Montreal, as part of a national GBM study, "Engage II". Engage II and Momentum are the same study with the name Momentum being used in Vancouver to relate it with earlier versions of the study. Vancouver, Toronto, and Montreal contribute equally to the total Engage dataset therefore there is no lead site. As such, your de-identified questionnaire data and testing lab results from the Momentum Health Study will contribute to Engage, and help contribute to a better understanding of GBM health and access to health services across Canada. As the Momentum study is a third of Engage the data we collect will contribute to the larger dataset combining with sites in Toronto and Montreal as well. As this is the nature of Engage and Momentum as the Vancouver site this contribution to the Engage dataset is not optional.

Your participation will involve collecting questionnaire data as well as providing some STI's test samples.

Questionnaire:

You will provide samples of blood to be tested for HIV, Hepatitis C, and syphilis (three small tubes of blood). You will also be asked to provide a urine sample and throat swab, and rectal swab sample, to be tested for chlamydia and gonorrhea. The computer-based questionnaire will take approximately 1-1.5hrs which you complete it on your own. You will be sent a secure study link through email to be able to complete the questionnaire remotely. If you do not have access to a computer/tablet or internet you can book an appointment to complete the questionnaire at our study site at St. Paul's hospital (1081 Burrard Street, 5th floor, Rm:B524). The questionnaire will cover the time period of the six months immediately prior to the interview. It will include questions on:

- participation in various community activities
- aspects of mental health,
- activities with recent sexual partners,
- drug use
- experiences of discrimination and trauma.
- attitudes and beliefs regarding HIV and STI risks
- the sexual norms in your social circles
- how you feel about the risks and responsibilities concerning HIV and other sexually transmitted infections.

Should any of the other questions cause you discomfort, you can select "prefer not to answer". For participants in distress resources can be found at the following link: https://www.healthlinkbc.ca/mental-health-substance-use/resources/crisis-intervention-and-suicide-prevention-centre-bc. You can also call a free 24 hour support line 310-6789 (no area code needed). Study staff can also provide resources from Health Initiative for Men (HIM), John Ruedy Clinic (JRC), Vancouver Coastal Health (VCH) mental health and substance use services as needed. The resources and links will also be available on our website so you do not have to interact with study staff when accessing those if that is a concern.

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Samples:

For your required testing you will be given the option of having a laboratory requisition mailed to you along with two swabs (for self-collection of throat and rectal specimens) and a urine cup, or going to study site room in St. Paul's hospital for biological specimen collection (1081 Burrard Street, 5fth floor, Room B524). Mailed requisitions may be taken to any laboratory (private or public) in greater Vancouver. All blood draws will be conducted by trained phlebotomists who are at the local labs (for participants who will do study testing with requisitions) or by a trained clinical nurse who has been hired as study staff (for those who choose to come in to the study site for collection).

There will be 3 required blood samples:

- one vial for HIV screening; 5mL/1tsp (or for HIV viral load 6mL/1.2tsp for participants known to be living with HIV)
- one vial 5mL/1tsp for syphilis and hepatitis C antibody testing
- and one vial 5mL/1tsp for Hepatitis C RNA testing,

The two swabs and urine sample will be for tests of chlamydia and gonorrhoea.

Results:

Results for your tests should be ready in approximately 7-10 days. If you wish, we can also have the laboratory send your results to your family doctor. The clinical component of your visit will take approximately 20 – 30 minutes.

In addition to this consent document, you will be provided with a Family Doctor Authorization consent and contact form seeking permission to contact your family doctor or attending specialist regarding your testing results and follow-up information (or download/electronically receive results from health information banks related to these study tests ordered by these physicians).

Recruiting Others:

At the end of the above procedures you may be provided with vouchers to recruit additional participants from among people you know. If you are eligible for the recruitment vouchers then detailed instructions will be provided on how to give them out in a confidential manner to eligible friends or acquaintances.

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

DATA AND HEALTH INFORMATION LINKAGES

Optional Linkage

Participation in the following will be completely voluntary and you will be asked separately at the bottom of this form to consent to this. Your questionnaire and STI testing information from the Momentum Health Study will be linked to health-related data held by the BC Centre for Excellence in HIV/AIDS, BC Centre for Disease Control, BC Ministry of Health, BC Vital Statistics Agency, the BC Cancer Agency, and the PharmaNet databases. This may include

information such as your CD4 count, viral load, and use of antiretroviral medications from the BC Centre for Excellence in HIV/AIDS, laboratory and testing information for HIV and STIs from the BC Centre for Disease Control, and doctor and other health- and drug-related information from the BC Ministry of Health, BC Vital Statistics Agency, BC Cancer Agency, via Population Data BC (e.g., data files such as Consolidation Files, Medical Services Plan Payment Information (MSP), Hospital Separations, Pharmacare, PharmaNet and Vital Statistics Registries will be requested). These data linkages will allow us to study how your use of health services affects your risk for getting STIs in the future, as well as how it affects other things such as physician visits and hospitalizations. We will request this data for up to 10 years after your consenting to this linkage.

This data linkage work will be done through the Comparative Outcomes and Service Utilization Trends (COAST) study. COAST is a study that aims to look the health outcomes and health service use of HIV-positive men and women, as compared to a random ten percent sample of the total population of British Columbia (BC). By consenting to this linkage you are consenting to allow your Engage data to be used in the work of COAST. This linkage will allow use to examine how the use of specific health services affects the development of sexually transmitted diseases in the future for both men living with HIV and those who are HIV negative. This research will be conducted by the same team of researchers._

For all data linkages, identifying information such as your name, date of birth and Personal Health Number will be used for matching purposes only. Matching is the process where we make sure that the data we have and the data we want to link is from the same person. Once the matching has been completed, all identifying information will be discarded and only an alias (e.g. xb100000009) will be used. The information needed for the matching process will be kept until the final data linkage is completed. At that point this identifying information will be deleted from all servers. Any matched information will be protected under the strictest provincial and federal privacy and confidentiality standards that apply to these health institutions and destroyed after the matching process is complete. Note that the optional data linkage will not be part of the Engage dataset mentioned above.

PARTICIPANT FOLLOW-UP

All participants:

You will not be contacted for negative or normal study results, but will be provided with the phone number for the study nursing office where you can call in to obtain these results. All positive or abnormal results will be reported back to you by your preferred method. The study nurse will contact you within two weeks to deliver the results of those laboratory tests by your preferred method of contact.

Participants with positive test results:

If you find out you have an STI, you may feel overwhelmed or upset. This is common, and the nurse is there to give you support. The nurse can answer your questions, talk about options and refer you to services that can help to support you.

For all positive tests, the study nurse will discuss with you the importance of returning to the study office, your primary care physician's office or other medical clinic for clinically

relevant follow-up and treatment, if needed. For newly positive HIV test results, you will be given a referral to a primary care clinic with expertise in HIV and linked with community agencies who provide support for people living with HIV. If not already completed in the study medical procedures, the nurse will draw two vials of blood for viral load and CD4 testing, as per standard clinical practice guidelines for those newly diagnosed. Copies of these results will be made available to your preferred primary care provider, if the you provided consent to do so. Similar procedures will be followed for new HCV positive tests. For positive syphilis, GC and CT tests, the study nurse, who will be certified in STI testing/treatment, will be able to administer treatment, in accordance with the standards of practice set by the College of Registered Nurses of British Columbia (CRNBC).

POTENTIAL RISKS OR DISCOMFORTS

Some of the questions will be on topics related to sexuality, drug use and trauma. It is possible that some of these topics might cause psychological discomfort if discussion of sexuality or drug use makes you uncomfortable.

Possible complications of drawing blood could include minor bruising, irritation, redness, minor bleeding and/or swelling where the blood is taken.

If you are not aware that you have a sexually transmitted infection then finding this out might cause emotional upset. All discussion about results will be done by our study nurse. They have provincial STI practice certification and over 10 years of experience in working in sexual health with men who have sex with men. They are very skilled in conveying information regarding STI testing, treatment and support. As such, all participants will be provided information about appropriate supports and linkage to care and treatment. You can also call a free 24-hour support line 310-6789 (no area code needed).

We do not anticipate any risks to you regarding the optional data linkages, as the study adheres to strict data management policies designed to protect the privacy and confidentiality of your personal information and health service data (described below in the section **CONFIDENTIALITY, DATA SECURITY AND PRIVACY**).

POTENTIAL BENEFITS

There may be no direct benefit to you by participating in this study; however, there are a number of potential advantages. You will access comprehensive screening for HIV and other STIs that are common among GBM. Responding to questions related to one's sexual practices on the behavioural questionnaire may elicit positive self-reflection.
We do not anticipate and direct benefits to you with respect to participating in the data linkage component of this study.

Participants in similar studies reported feeling gratified for having contributed to the advancement of research. We anticipate that the findings from this study will have benefits for GBM in Metro Vancouver, across British Columbia, and across Canada.

WITHDRAWAL FROM THE STUDY

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You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please contact the study coordinator or one of the principal investigators through the contact information listed on the last page of this consent form.. If your participation in this study includes enrolling in any optional studies, or long-term follow-up, you will be asked whether you wish to withdraw from these as well.

CONFIDENTIALITY, DATA SECURITY AND PRIVACY

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the Canadian Institutes of Health Research or the University of British Columbia Providence Health Care Research Ethics Board or the University of Victoria Research Ethics Boards, 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 security for Linkage to COAST:

The same data security for Engage applies to any work done with the linkage to COAST. All data files will be encrypted, password protected and stored on a secure server located in a highly secure area at the BCCfE. All survey data will be stored separately from personal data. The server is located in a highly secure area of the BCCfE that is accessible only to the authorized IT staff. Only the investigators, study staff key members of the study team (namely data managers and statisticians) will have access to the electronic data.

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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 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 staff.

Reportable Diseases

Your personal information or information that could identify you will not be revealed without your express consent unless required by law. If facts become known to the researchers which must be reported by law to public health authorities or legal authorities, then your personal information will be provided to the appropriate agency or authority.

The specific reportable diseases being tested for in this study are:

- HIV
- Syphilis
- Hepatitis C
- Chlamydia
- Gonorrhea

Your biological samples for STI testing will be sent to the Provincial Health Services Authority Laboratory at the BC Centre for Disease Control (BCCDC) or Providence Health Laboratory at St. Paul's Hospital along with the following identifying information: first name, last name, Personal Health Number and date of birth. This information sent to the laboratories will be protected under the strictest provincial and federal privacy and confidentiality standards that apply to these health institutions. However, as HIV and STIs are mandated reportable diseases, all new positive tests will be forwarded to the public health agencies such as the BCCDC , Vancouver Coastal Health or Fraser Health for follow-up by public health nurses to ensure appropriate treatment and follow-up and to assist with partner notification.

Information Storage

Questionnaire data and test results and will be stored securely at the BCCfE. Any digital data is entered through secure webforms which are linked over a private network to a secure server. Any paper forms are kept at secure premises of the BC Centre for Excellence in HIV/AIDS (BCCfE) (1081 Burrard, 5th floor Room 62013).

LEGALLY REQUIRED INFORMATION DISCLOSURES

Disclosure for health care purposes

To process your laboratory tests, your first name, last name, date of birth and personal health number will be needed.

Your personal information or information that could identify you will not be revealed without your express consent unless required by law. Reports or allegations of abuse will be reported to the proper authorities such as Ministry of Children and Family Development – Province of British Columbia. We believe that the questionnaire, however, does not contain questions that could be used by legal authorities to criminalize your reported past behaviours.

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REMUNERATION/COMPENSATION

In order to recognise your valuable contribution to the study and to defray costs of any inconvenience or lost wages, you will be offered an honorarium valued at $50 for participation in this study. The honorarium will be offered as cash or etransfer based on your preference. You will also receive an additional $15 per recruiting voucher for successful recruits, also as either cash or etransfer.

WHAT IF SOMETHING GOES WRONG?

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.

CONTACT FOR INFORMATION ABOUT THIS STUDY

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact:

Vancouver Principal Investigators:
Dr. David Moore, (604) 806-8478, dmoore@bccfe.ca
Dr. Nathan Lachowsky, (250) 472-5739, nlachowsky@bccfe.ca

Vancouver Study Coordinator:
Allan Lal, 604-682-2344 ext. 62013 alal@bccfe.ca

CONTACT INFORMATION ABOUT THE RIGHTS OF RESEARCH SUBJECTS

University of British Columbia:
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 H24-02085 when calling so the Complaint Line staff can better assist you.

DISSEMINATION OF RESEARCH RESULTS

Plain language (i.e., non-technical language) updates and reports of the study results will be made available on the study web page on the website of the BCCfE at www.momentumstudy.ca.. Findings will also be presented at scientific conferences and in articles in scientific journals. We will also be working with various local community-based organizations to disseminate research findings in plain language and accessible formats.

No information that can identify an individual is ever used in these updates and reports or in presentations or articles.

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PARTICIPANT CONSENT

My signature on this consent form means:

- I have read and understood the study information and consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary
- I understand that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my health record as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand the risks that are related to the requirements for disclosure of information to the Ministry of Health.

I will receive a signed copy of this consent form for my own records.
I consent to participate in this study.

_____	_____	_____
Printed name of Participant	Signature	Date
_____	_____	_____
Printed name of Principal Investigator/Designate	Signature	Date

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES

As part of the national GBM study, **Engage II**, there may be future studies covering similar research topics that you may be eligible for (with additional incentives for participation), including a face-to-face interview with a researcher. Would you be willing to be **contacted in the future** by a researcher to provide you with information about such research studies?

❑ **YES,** I would like to be contacted about future Engage-related studies that I may be eligible for

❑ **NO,** I am not interested in being contacted about future Engage-related studies

Optional Health Record Linkages

With your consent we would like to link your questionnaire data with administrative health and laboratory data as outlined above.
You do not have to consent to data linkage to participate in this study.

❑ YES, I consent for my questionnaire data to be linked with administrative health and laboratory data held by the BC Ministry of Health

❑ NO, I do not consent