LEADING-MH Study

Principal Investigator: Dr. Steven Reynolds

What is this study about?

This study looks at how a lab test could help doctors diagnose and treat depression, psychosis, and schizophrenia. Scientists think the test results may show who will respond to certain medications. The goal is to improve mental health care.

What will you be asked to do?

You will have up to three study visits over 6 months, each lasting about one hour. At each visit, you will:

- Answer mental health questionnaires (you can skip any question).
- Give a small blood sample at the hospital lab.
- Allow researchers to check your medical records.

What are the risks?

- Time commitment: Each visit may take up to 1.5 hours.
- Blood tests: You may feel mild pain, bruising, or dizziness.
- Emotional discomfort: Some questions may cause stress or anxiety.
- Privacy concerns: Your name will be removed from study records, but in any study, there is a small risk of data leaks.

Access Study Website

Do you have any questions?

(236) 332-6575 (24/7)

LeadingMH@fraserhealth.ca

rchfoundation.com/leading-mh-study/

Participant Information and Consent Form

Title: Lymphocyte Membrane Proteins Cluster Analysis as a Novel Differential Diagnosis and Drug Efficacy Biomarker in Mental Health: **LEADING-MH**

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Research Site: Royal Columbian Hospital (RCH)

Funding Agency: Advancing Innovation in Medicine Institute (AIM), Royal Columbian Hospital Foundation

Study Contact Information: Call (236) 332-6575 (available 24 hours/7days a week) or email to LeadingMH@fraserhealth.ca

INVITATION

You are invited to participate this study because you have indicated interest, and/or have been diagnosed with, or may have, depression, psychosis, or schizophrenia and are receiving care at the Royal Columbian Hospital Psychiatric Clinics. Participation is voluntary. If you decide not to take part or choose to stop being in the study at any time and for any reason, you will not lose any benefits you would normally have, and it will not affect the quality of care you receive.

WHAT IS THE PURPOSE OF THE RESEARCH STUDY?

Mental health conditions like depression, psychosis, and schizophrenia can be challenging to diagnose and treat. Unlike other medical fields that use lab tests, psychiatry relies on observing symptoms and trying different treatments, which can take time.

Recent research shows that certain proteins in the blood change in people with depression, bipolar disorder, or schizophrenia. These changes may also help predict how well someone with depression will respond to medication. To study this, researchers analyze blood samples under a microscope to examine these protein patterns.

This study aims to see if certain proteins in white blood cells (lymphocytes) can help diagnose depression, psychosis, and schizophrenia at the Royal Columbian Hospital Psychiatric Clinics. Researchers want to find out if these protein changes can predict who will respond to medication, distinguish between a single-episode psychosis and schizophrenia, and establish whether these protein patterns differ in individuals who are not currently experiencing any mental health conditions.

WHO CAN JOIN THE STUDY?

Up to 500 people will take part in this study at the Royal Columbian Hospital's Psychiatric Outpatient Clinic, the Early Psychosis Intervention (EPI) Clinic, and the Psychiatric Urgent Referral (PUR) Clinic in New Westminster. Additionally, up to 100 people from the general public will participate as the control group. The study will take about 12 months, with results expected in 18 months.

WHAT WILL HAPPEN IN THIS STUDY?

If you join, you will have up to three study visits (initial, 3-month, and 6-month follow-ups), each lasting about one hour. These visits may or may not align with any scheduled clinic appointments. Researchers need multiple visits to track changes in your biomarkers and questionnaire responses over time.

You will be placed in one of three groups:

- Depression Group (if you have or may have depression).
- Psychosis Group (if you have or may have psychosis or schizophrenia).
- Control group (if you do not have history of any major psychiatric condition).

First Visit

- We will collect basic details (birth month/year, sex at birth, optional ethnicity).
- Your medical records will be reviewed for diagnosis, medications, family history, and recent bloodwork.
- You will complete mental health questionnaires on mood, anxiety, substance use, and alcohol use. Additionally, if you are in the Psychosis group, a clinician will administer a questionnaire to gain further insight into your condition.
- You will have a small blood sample taken (13.5 mL, two vials) at the hospital lab, with a research coordinator assisting you.

Follow-up Visits (3 and 6 months)

- You will complete the same questionnaires as the first visit.
- You will have another small blood sample (13.5 mL, two vials) taken at the hospital lab, with a research coordinator assisting you.

You can skip any questions you do not want to answer.

POSSIBLE RISKS AND DISCOMFORTS

Participating in this study may involve some risks and inconveniences:

- Time Commitment: Each visit takes about one hour. We will try to schedule visits on the same day as your regular clinic appointments.

- Physical Risks: Blood draws may cause mild pain, bruising, bleeding, or dizziness. In rare cases, infection can occur. To reduce these risks, trained professionals will perform the blood draw using safe techniques.

- Emotional Risks: Answering questions about mental health may cause stress or anxiety. You can skip any question that makes you uncomfortable.

- Privacy Risks: Although we follow strict confidentiality rules, there is a small chance of accidental data sharing. To protect your privacy, we remove your name, assign a study code, and store records securely.

- Risks for the Control Group: Even if you do not have a history of mental health conditions, your responses on the questionnaires may suggest a possible mental health concern. With your permission, this information may be shared with you and/or your primary care practitioner so they can offer you appropriate support.

This study will ask about sensitive topics, but the research team does not provide mental health services. If you need support, we have included several resources on the last page of this document (Appendix I).

BENEFITS OF PARTICIPATING

You may not receive direct benefits from this study. However, your participation may help improve how mental health conditions are diagnosed and treated in the future.

The mental health questionnaires you complete are part of standard care. If you agree, we can share your results with your healthcare team at Royal Columbian Hospital or with your primary care practitioner (Control group) to help guide your treatment.

ALTERNATIVES TO PARTICIPATION

If you choose not to join this study, any medical care that you may be receiving will not be affected.

CAN I LEAVE THE STUDY?

Yes, you can leave the study at any time without giving a reason. If you decide to withdraw, please contact the study doctor or staff. You can also ask us to stop using your information by contacting any member of the research team.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

We will only collect the information needed for this study. Your personal details will remain confidential, as required by law. Your privacy will be protected at all times.

You will be identified by a unique study number instead of your name. This number may link to details like your age, sex, and visit dates, but not to your Personal Health Number, SIN, or initials. Your study records, along with the key that links your name to your study number, will be stored securely and will only be accessible to the Principal Investigator and authorized research staff.

In addition, representatives from the Fraser Health Research Ethics Board (FHREB) may review your study records to ensure the research is being done properly. They will see study data, but not your name or other personal details.

Your information will be stored securely and kept confidential for five years. It will not be shared or published without your consent, unless required by law. You also have the right to access your information and correct any errors. If you have questions about privacy laws, you can ask the Principal Investigator.

WHAT ARE MY RESPONSIBILITIES?

If you decide to participate, you will be expected to:

- Read the consent form and ask any questions you may have.
- Sign and date the consent form.
- Inform the research team if you decide to withdraw.
- Contact the study team or Research Ethics Board if you have concerns.
- Keep a copy of this consent form for your records.

WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this form does not take away your legal rights or release the study doctor or hospital from their responsibilities.

If you become sick or injured from this study, medical treatment will be provided at no cost to you. Your provincial medical plan will cover the expenses.

WILL THIS STUDY COST ME ANYTHING?

There are no costs to you or your health insurance for participating. All study-related care and tests are provided free of charge.

For every study visit, parking and public transportation costs will be covered by the study.

WILL I BE PAID FOR THIS STUDY?

You will not be paid, but you will receive a $20 gift card after every study visit, as a thank-you for your time and effort.

WHAT WILL HAPPEN ONCE THE STUDY IS COMPLETED?

After the study ends, individual results will not be shared. However, overall findings will be shared through journal articles, presentations, and our website so that participants and the community can learn about the results and what they mean.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have questions or need more information before or during the study, or if you experience any issues, contact the LEADING-MH Study Team at:

(236) 332-6575 (24/7)
LeadingMH@fraserhealth.ca

WHO DO I CONTACT ABOUT MY RIGHTS AS A PARTICIPANT?

If you have questions about your rights as a research participant or your experience in this study, contact the Fraser Health Research Ethics Board (REB) Chair at:

604-587-4681 (Reference Study FHREB #2024143).

SHARING STUDY DATA WITH YOUR MEDICAL CIRCLE OF CARE

Do you agree to share your questionnaire results and bloodwork analysis with your healthcare team at RCH?

☐ Yes _____ Initials

☐ No _____ Initials

SHARING YOUR RESULTS WITH YOUR PRIMARY CARE PRACTITIONER (CONTROL GROUP ONLY)

If you are part of the CONTROL group, you are joining the study as someone without a history of mental health diagnoses. However, your answers on the questionnaires still might show signs of depression, anxiety, or other concerns.

Would you like us to share your results with your primary care practitioner if we notice any signs of a mental health condition? If you do not have a primary care practitioner or do not know their name, the study's Principal Investigator will contact you directly to share the results.

☐ Yes _____ Initials

☐ No _____ Initials

If yes, please write your doctor's name and clinic information (if known):

_____

Important Note: If we identify serious signs of distress, self-harm or suicidality, we will need to take steps to ensure your safety. This may involve contacting you directly to recommend that you visit the nearest Emergency Department or reaching out to your primary care practitioner if we have their contact information, even if you have not given explicit consent for us to do so.

Participant Information and Consent Form

Title: Lymphocyte Membrane Proteins Cluster Analysis as a Novel Differential Diagnosis and Drug Efficacy Biomarker in Mental Health: LEADING-MH

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records 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 that there is no guarantee that this study will provide any benefits to me.

The Participant and the investigator are satisfied that the information contained in this consent form was explained to the Participant to the extent that they are able to understand it, that all questions have been answered, and that the Participant consents to participating in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Signature of Participant	Printed Name	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	Printed Name & Role	Date
_____	_____	_____
Investigator Signature	Printed Name	Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant's signature was obtained.

Complete the following section only if the participant is unable to read, requires an oral translation or a translator:

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

☐ Yes ☐ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check "no".]

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed Name	Date

APPENDIX I: Support resources.

- **Fraser Health Crisis Line – (604) 951-8855 or 1 (877) 820-7444** (24/7 free and confidential support).

- More resources: Options Community Services Website: https://www.options.bc.ca/program/fraser-health-crisis-line

- **9-8-8 Suicide Crisis Helpline**: Call or text **988,** 24 hours a day.

- **In the event of a medical emergency go to the nearest emergency department or call 911**

- **Alcohol & Drug Information and Referral Service**

  Phone: +1 (800) 663-1441 Lower mainland – (604) 660-9382

  Available to people across BC needing help with any kind of substance abuse issues 24/7

- **Multilingual Distress Line**: Provides emotional support, crisis intervention, and suicide prevention for at-risk individuals in Peel Region in English, Cantonese, Mandarin, Portuguese, Spanish, Hindi, Punjabi, and Urdu. Available Monday–Friday, 07:00 AM–07:00 PM PST.

  Phone: (905) 459-7777

- **National Indian Residential Schools Crisis Line**: This 24/7 national service offers crisis support to former Residential School students, provided by trained Indigenous counsellors.

  Phone: +1 (866) 925-4419

- **Naseeha**: An international hotline offering Muslim youth and others confidential support on mental health, addiction, bullying, relationships, religion, and work-related issues. Peer counsellors provide anonymous phone support daily (12:00–9:00 PM) and text support Monday–Friday (12:00–9:00 PM).

  Call or text: +1 (866) 627-3342 (NASEEHA)

- **Here to help:** Online resource offering information for managing mental health and substance use.
  Website - https://www.heretohelp.bc.ca/