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PARTICIPANT INFORMATION SHEET

Title of Study: Pharmacogenomics-Supported Psychotropic Prescribing Trial (PGx-SUPPORT): A Pilot Implementation Study in Manitoba

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You are being asked to participate in a research study. Please take the time to review this information sheet and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family, or your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information you do not clearly understand.

Purpose of Study

This research study is being conducted to study if pharmacogenomic testing is helpful in selecting medication for adults receiving mental health services in Manitoba. Genetics impact how fast or slow an individual person processes different medications in their body. Pharmacogenomic testing provides prescribing recommendations based on a person's genes responsible for processing these medications. Although pharmacogenomic testing cannot predict which medication will work best, it can help to reduce some of the trial-and-error time in selecting medications and help to limit side effects.

There are currently guidelines on using pharmacogenomic testing to select medications for mental health and a variety of other conditions. However, this testing is currently only available through private companies in Canada. We want to understand if physicians and their patients in Manitoba find pharmacogenomic testing useful for selecting medications for mental health when it is available at no cost.

A total of 200 participants will participate in this study.

Study Procedures

If you take part in this study, you will have the following procedures:

1. Questionnaires:
    - You will complete questions about yourself. This information will include:
        - *i.* Demographics (age, sex, ethnicity, etc.)
        - *ii.* Contact information (address, phone, email)
        - *iii.* Medical information (medication, health resource use etc.)
        - *iv.* Clinical assessment (side effects, mental health questionnaires)
        - *v.* Satisfaction questions about the pharmacogenomic testing
    - These questionnaires can be completed on-site at the clinic from where you are receiving services or online.
    - These questions are done twice, once when you enter the study and again after three months.
    - These questions take an average of 45 minutes to complete.
    - You may complete all the procedures with the help of your caregiver(s).
    - We request that you let us know via e-mail or phone once you are discharged from the clinic so that we can contact your doctor

2. Saliva sample:
    - You will provide a one-time saliva sample. You will rub a small sponge in your mouth to collect some saliva (one-fifth of a teaspoon, 1 ml) that contains DNA.
        i. We ask that you not eat, drink, smoke, or chew gum for 30 minutes before doing this.

- The saliva sample collection will usually be done in-person at the clinic that you are receiving services from. In some cases, you may be mailed a saliva kit to your home with the return postage pre-paid for you.

- Rarely, we may ask you to provide a second saliva sample if the genetic analysis from the first saliva sample fails.

- The saliva will be processed at the University of Calgary. DNA will be extracted from the saliva for genetic analysis. We will look at your genes and prepare a pharmacogenomic testing report.

3. Health record access:
    - The study team will access medical record information on your medication history, mental health services and health care utilization, neighborhood socioeconomic status, and diagnoses for six months before and after you participate in the study. For this purpose, we will collect your full name, date of birth, and personal health identification number (PHIN). By signing this consent form, you authorize the research team to access your individually identified health information for research purposes from various data custodians in Manitoba that store your medical information and administrative data.

Schedule of Study Procedures

	Baseline (study entry)	Three months	Six months (pre-and post-study entry)
Completed by you			
Consent Form	X		
Demographics	X		
Medication information	X	X	
Clinical questionnaires	X	X	
Saliva sample	X		
Satisfaction questions		X	
Completed by the study team			
Health record access			X

Depending on your medical condition(s), the questionnaires/surveys (baseline and 3-month follow-up) will take up to 45 minutes to complete. Saliva collection will take an additional 10 minutes or less to complete at baseline.

Participation in the study will be for three months. Health record access is for six months before and after entering the study.

You can stop participating at any time. However, if genetic data has already been used to prepare the pharmacogenomic testing report and sent to you and your doctor, retracting your report will not be possible. If you decide to stop participating in the study, we encourage you to talk to the study staff first. Your research data and DNA sample will be destroyed wherever possible. Published data cannot be destroyed.

Saliva samples will be sent to the University of Calgary via postal mail. Pharmacogenomic testing will be done at Alberta Precision Laboratories or another accredited clinical laboratory through our research collaborator (Dr. Bousman, study co-investigator) at the University of Calgary. Genetic results and any remaining DNA samples will be returned from the University of Calgary to the Principal Investigator's Lab at the University of Manitoba. By signing this consent form, you consent to transfer your saliva samples and research data to and from the researchers at the University of Calgary and Alberta Precision Laboratories or another accredited clinical laboratory. If you do not consent to long-term storage of your genetic material, your DNA will be destroyed within two weeks of providing you with the pharmacogenomic testing report.

A pharmacogenomic testing report will be provided to you and your doctor approximately two weeks after it has been received at the lab at the University of Calgary. Your doctor may use the information for your medical care. Your doctor may also store the test results in your medical record.

Your research data from the study will be securely stored at the University of Manitoba College of Pharmacy for seven (7) years after the study is complete, approximately up to 2035. After that, your samples will be destroyed, and all your identifying information will be erased (i.e., your data will be de-identified).

You can also provide "optional" consent to let us keep your deidentified DNA sample and research clinical and genetic data for 30 years after the study is complete, approximately up to 2058, for future research. The Principal Investigator will be the custodian of your data.

Some research data and DNA samples from the study, which are being kept at the University of Manitoba, may be shared with researchers, academic institutions, healthcare facilities, or organizations outside of the University of Manitoba for further analysis, testing, or as part of the research study. Any information or DNA samples that is/are shared will not show your name or address or any other identifiable personal information about you.

Upon request, a summary of study results can be provided to you once they are available.

Risks and Discomforts

There are no known risks of rubbing a small sponge in your mouth to collect saliva. You may become frustrated or tired when completing questionnaires. You can take a break if any questions make you feel uncomfortable. You may stop at any time.

Your condition may not improve or may worsen while participating in this study.

Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you. Due to the rapid pace of technological advances in genetics, there may be a risk that the genetic information in the sample and data could be linked back to you. There is also a risk of unintentional release of information. The potential re-identification or unintentional release of your information could lead to loss of privacy and possible future discrimination against you or your biological relatives. The potential future use of genetic information is unknown, and therefore, not all potential future risks are known.

Incidental/Unexpected Findings

If you participate in this study, we will sequence specific parts of your genome. We are not investigating any genetic or other hereditary medical disorders. We will examine a small number of genes known to affect how our bodies process medications. They are not currently linked to a particular disease or risk for future disease. However, future research may lead to finding other medical information linked to these genes. There is a chance this could reveal a medical condition or risk for a medical condition. This would be considered an “incidental finding”. This information may affect your health and/or your ability to work in certain professions and obtain life or health insurance, among others. As genes are hereditary, the identification of an incidental finding could also have implications for biological (blood) family members, such as parent(s), sibling(s) and child(ren). Please take your time to consider this carefully.

We would only return information on incidental findings that are medically actionable (i.e., a treatment or prevention option is available) and if they are discovered within 2035.

It is “optional” to learn about incidental findings. If you consent to be notified about incidental findings, we will ask for your contact information (email address or phone number). If we discover any incidental findings about you, we will consult medical specialists (Medical Geneticists, Genetic Counsellors) at the University of Manitoba to confirm if the findings are medically actionable. If they are medically actionable, we will contact you and discuss how you want to receive this information. We will work with you and your doctor(s) during this process. Any medically actionable incidental findings need to be validated in a clinical laboratory. This will be discussed with you and the doctor involved in your care, and appropriate referrals will be initiated. Your decision to receive medically actionable incidental findings can be indicated on Page 9 of this Consent Form. You can withdraw this consent at any time by contacting the study team.

Benefits

There may or may not be a direct benefit to you from participating in this study. We hope the information learned from this study will benefit other people who are prescribed medication(s) for mental health in the future.

The pharmacogenomic report provided to your doctor may help with decisions about which medication to prescribe and/or at what dose. This does not guarantee that the medication will work well for you or not cause side effects, but this study is intended to increase this chance.

Payment for participation

You will be given a $25 e-gift card:

- after completing the baseline study procedures and sending us the saliva sample
- after completing the three-month questionnaires

for a total of $50 possible payment.

Costs

All the procedures that will be performed as part of this study are provided at no cost to you.

Commercialization

It is possible that the research conducted using your DNA samples and/or research/genetic data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. However, you will not receive any financial benefits or intellectual property rights from your participation.

Alternatives

You do not have to participate in this study to receive treatment for your condition. Please talk to your regular doctor (or therapist) about all your treatment options.

Confidentiality

Information gathered in this research study may be published or presented in public forums. However, your name and other identifying information will not be used or revealed. Once you are enrolled in the study, you will be assigned a unique study ID that does not identify you. Your data will be identified by this study ID rather than your personal information, such as your name or telephone number.

Increasingly, the scientific community, granting agencies, and medical scientific journals require that data be stored and made available for secondary review and analyses. For publication purposes, your de-identified study data may be shared with/sent to other researchers from other institutions for secondary analyses or other research purposes.

Your saliva will be processed at the University of Calgary, and Pharmacogenomic testing will be done at Alberta Precision Laboratories or an accredited clinical lab facilitated by our collaborator at the University of Calgary. Genetic results and any remaining DNA samples will be returned from the University of Calgary to the Principal Investigator's Lab at the University of Manitoba. An agreement will be in place between these two organizations to ensure data security and confidentiality.

Your full pharmacogenomic testing report will be provided to you and your referring doctor. The pharmacogenomic testing report will contain your name initial, date of birth, pharmacogenomic testing results, and current medication or supplement information (if applicable). Your doctor may add the pharmacogenomic testing report to your medical record. Medical records that contain your identity will be treated as confidential in accordance with the *Personal Health Information Act* of Manitoba. Your genetic results are protected in accordance with the *Genetic Non-Discrimination Act* of Canada.

We will store your DNA at the University of Manitoba College of Pharmacy in a secure research facility. We will store them as de-identified data/samples (your name will not be on these records). We will keep a master list connecting your name to your study ID in a secure location, separately from other data. Only designated study staff have access to the master list. We will store your research and genetic data in data storage files or online servers authorized by the University of Manitoba. All data storage files will be locked with passwords in a locked, secure office.

All records will be kept in a locked, secure area, and only designated study team members will have access to them. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address, or telephone number will leave the University of Manitoba.

Despite protections in place, there is a risk of unintentional release of information. Genetic information may also be linked back to you due to technological advances in genetics. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law or professional obligations of the researcher.

The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate, or you may withdraw from the study at any time. However, if genetic data has already been used to prepare the pharmacogenomic testing report and sent to you and your doctor, retracting your report will not be possible.

If you want to withdraw your research data, please notify Dr. Abdullah Al Maruf in writing. Your research data will be destroyed whenever possible. If your data has already been included in the final study analysis, it will not be possible to withdraw it from that analysis.

Your decision not to participate or to withdraw from the study will not affect your care at this unit. If the study staff feel that it is in your best interest to withdraw you from the study, they will remove you without your consent. The researchers or the University might also decide to stop the study at any time and destroy all samples and research/genetic data.

We will inform you of any new information that may affect your health, welfare, or willingness to stay in this study.

(Optional) Use of DNA samples and Research Data for Future Research

If you consent to long-term storage, we will store your DNA sample and clinical and genetic data for seven (7) years after the study is completed, approximately until 2035. After these 7 years have passed, all identifiable information will be erased, and all genetic material will be destroyed. Only de-identified clinical and genetic data will then be retained for 30 years, approximately up to 2058, for future research to learn about, prevent, or treat mental health-related conditions, to study variability in medication response, or to understand genetic predispositions linked to genetic and chronic diseases.

This is entirely optional. You will not be re-contacted for this purpose.

We will store your clinical/genetic data in data storage devices or online servers authorized by the University of Manitoba. All data storage devices will be locked with passwords in a locked office. All records will be kept in a locked, secure area, and only designated study team members will have access to them.

We may securely send and share de-identified DNA samples and data to other local or international researchers, academic institutions, healthcare facilities, or public or private organizations (for-profit or not-for-profit) within and outside the University of Manitoba for further genotyping (including whole genome – long read, short read or exome sequencing), data banking, data analyses, or publication purposes as part of future research. We will ensure that outside laboratories or institutions maintain the safety and security of the samples/data. We would only return information on incidental findings that are medically actionable (i.e., a treatment or prevention option is available) as described on Page 5.

Separate Research Ethics Board approvals for stored DNA samples and research/genetic data will be obtained for all future studies. You can withdraw your consent at any time by contacting the study team.

(Optional) Contact for Future Research

The researchers involved in this study may contact you in the future to ask if you would like to participate in other research studies. These studies would aim to learn about, prevent, or treat mental health-related problems, find better treatment options, or understand genetic predispositions linked to genetic and chronic diseases.

Questions

You are free to ask any questions that you may have about your treatment. If any questions come up during or after the study or if you have a research-related injury, contact the study doctor(s) and the study staff at (431) 294-7781 or pharmpgxlab@umanitoba.ca

(Optional) I agree to be contacted for future follow-up in relation to this study.

❑ YES ❑ NO

(Optional) I wish to be contacted in the case of a medically actionable incidental finding by 2035.

❑ YES ❑ NO

(Optional) I agree to store my de-identified research and genetic data until 2058 for future research.

❑ YES ❑ NO

(Optional) I agree to store my DNA samples until 2035 for future research.

❑ YES ❑ NO

(Optional) I wish to be contacted by the research team to participate in other research studies.

❑ YES ❑ NO