LETTER OF INFORMATION
CAMH Pharmacogenetics Program
IMPACT Study

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CONFLICTS OF INTEREST DISCLOSURE - The Investigators do not have any conflicts of interest regarding this study.

INTRODUCTION
You are eligible to participate in this research study because you are either currently taking psychiatric medication or your physician is considering prescribing psychiatric medication for you in the near future. Some people can experience side effects from these drugs and/or some people can respond poorly to them. The way a person responds to a drug and its side effects are primarily due to genetic factors. For example, your particular genetic factors determine the way you break down your medication and if you are more or less likely to develop side effects.

PURPOSE OF THE STUDY
We would like to better understand how differences in people’s DNA affects the way they respond to certain psychiatric medications. Genetic testing of your liver enzymes and other genes will give an idea of how quickly you will break down certain antidepressant and antipsychotic medications. It could also tell us whether you might need a different dose of a medication and your likelihood of having some side effects.

We will also look at your DNA to see if we can find new gene variants that may cause you to experience treatment side effects, like gaining weight or muscle stiffness. The overall purpose of this research study is to better understand how DNA differences among people on psychiatric medications affects their response to psychiatric medication.
DESCRIPTION OF THE STUDY PROCEDURE

Study Entry
If you agree to enroll in this study you will be directed to our online study questionnaires. In particular, you will be asked questions about your medical history including details about the symptoms you had and how they changed over time, and details about side effects that are or were potentially related to your medication. You will be asked in detail about your current symptoms using some questionnaires that may take up to 30 minutes to complete.

We will also ask you to provide some of your saliva (approximately half a teaspoon) as a sample for DNA testing. An interpretation (but no DNA data) from these findings will be given to your referring physician.

We will also ask you to provide your OHIP number. We will use it to collect data on the medical activities and costs associated with your OHIP number (not your name) as recorded in the Institute for Clinical Evaluative Science, for the time spanning the three years before and after study entry.

Follow-up
These will take place at 4 and 8 weeks after study entry. You will be contacted by email and asked to visit our website to complete questionnaires on which medications you are currently taking and any effects or side-effects you are currently experiencing. This questionnaire will take about 15 minutes to complete.

BENEFITS
You will receive no direct benefit from your participation in this study. However, this study relies on your participation in order to increase our understanding of how DNA affects response to, and side effects from, some psychiatric medications. Findings from this study may benefit people with an increased risk for of side effects from psychiatric medications and may help to find new treatments for psychiatric illnesses.

RISKS
If you consent to give a blood sample for this study, the risks and discomforts of giving a blood sample are the same as those for any blood taken from a vein. There may be minor bruising or irritation. In rare cases, there may be local infection.

CONFIDENTIALITY AND PRIVACY
To protect your confidentiality, Dr. Kennedy’s team will label (‘code’) your blood and/or saliva sample and all your medical information with a number, not your name. This number will be how researchers keep track of samples and information.

The study staff (for example, investigators, research staff and lab technicians) will not store your Informed Consent or any information you provide in your medical records. Your name will not be in any publications or external reports about this research. The investigative team will control access to files that hold your medical information and results. Your physician will receive an interpretation of the genetic results and may or may not choose to keep that in your medical records.
Your questionnaire information and any coded results will be put on a computer and stored securely in an electronic database. When processing and storing personal information, we will comply with the relevant laws that protect the confidentiality of all research participants.

All reasonable measures to protect the confidentiality of your study records and their identity will be taken to the extent permitted by the applicable laws and/or regulations, and will not be made publicly available. The results of this study may be presented at meetings or in publications; however, your identity will not be disclosed.

We may collaborate with other research organizations in other locations, including commercial companies, who may want to use your sample and already collected medical information for studying genetic material and substances related to research on psychiatric disorders. Your name will not be released; we will require that other collaborators keep your de-identified medical information confidential.

As part of continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board. A person from the research ethics team may contact you (if your contact information is available) and ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain your confidentiality to the extent permitted by law. In addition, as part of the Research Services Quality Assurance Program, this study may be monitored and/or audited by a member of the Quality Assurance Team. Your research records and CAMH records may be reviewed during which confidentiality will be maintained as per CAMH policies and extent permitted by law.

Dr. Kennedy’s team has taken all reasonable steps to protect your research information. This is done to reduce the potential harm to you from an unintended disclosure of genetic or personal information. We will not give your genetic research results to anyone other than your doctor, unless required by law. However, even with these precautions and although your sample and your personal information are coded, we cannot guarantee that a connection between you and your results will not be established.

**DURATION AND SCOPE OF THE STUDY**

Your participation in this study will take approximately two months. The entire study is expected to take about 6 years to complete and the results should be known within one year following the completion of study procedures. It is expected that 20,000 people from across the province of Ontario will take part in this study.

**STORAGE OF INFORMATION AND MATERIALS**

**Materials**

All DNA samples will be stored at the Centre for Addiction and Mental Health in an access-restricted refrigerator. Any samples obtained from you will be destroyed once analysis is complete.

If the research study is extended beyond this time, you will be asked to give consent to extend the storage period for a specified amount of time. If you cannot be reached, your IMPACT Study – Adult Informed Consent Form Version 4.0 Dated: 08/05/2014 Page 3 of 5
samples will be destroyed at that time.

**Information**

Your personal information will be retained for seven years from the end of the study period. At this time, all study data including paper copies of questionnaires, electronic database, and other study documents that contain your personal information will be securely deleted. If you decide to withdraw your participation at any point in the study, you have the right to permit or restrict the use of your data for research purposes. If you should choose to limit the use of your data, then the information you provided during the study will no longer be used.

**ANTICIPATED EXPENSES**

You will receive $20 for taking the time to visit our IMPACT Assessment Centre, to complete the procedures at study entry (completing questionnaires and providing saliva sample). If you agree to participate in a follow-up visit to provide a blood sample, you will receive $20 to cover your transportation costs.

**COMMERCIAL USE OF INFORMATION GATHERED**

The results of this research may be used for commercial and/or intellectual property (for example, patents) purposes for our group, or to another party to which we might license or sell them. If this results, you will not receive any further financial compensation.

**YOUR RIGHTS**

1. You have the right to withdraw from the study at any time and that this withdrawal will not affect your future medical treatment at CAMH.
2. By giving consent, you do not give up any of your legal rights.

**YOUR RESPONSIBILITIES AS A PARTICIPANT**

Although participation in this study is entirely voluntary, you are responsible for completing the full procedure during each interview. If you choose to not provide a saliva OR blood sample, you may not be able to participate in the study.

**VOLUNTARY PARTICPATION AND WITHDRAWAL**

You may choose to end your participation in this study at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care at CAMH. There will be no penalty or loss of benefits to which you are otherwise entitled. If you withdraw consent to participate after beginning the study, the data collected up to that time point will be used and your doctor may keep the interpretation of your genetic test in your medical records.

**CONTACT INFORMATION**

If you have any questions about this study or wish to withdraw from this study, please contact the principal investigator: Dr. James Kennedy at 416-979-4987. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call Dr. Padraig Darby, Chair of the Centre for Addiction and Mental Health Research Ethics Board at 416 535-8501 ext. 6876.
By checking the box provided, I confirm that:

- I voluntarily agree to participate in this research study.
- I understand the requirements of participating in this research study.
- I have been informed of the risks and benefits, if any, of participating in this research study.
- I agree that my OHIP number may be used to access and collect information about the times I visited doctors/hospitals and the types of medical tests/services I had over the past three years and may have during the next three years.
- I understand that I am free to withdraw from the study at any time and that this withdrawal will not affect my future medical treatment at CAMH.
- Information will be treated in the strictest confidence. However, I understand that information from my medical records might be needed for my involvement in the study to obtain research information, such as response and side effects to previous and current medications.
- I understand that my Personal Health Information (PHI), with my permission, will be accessed for the purpose of this study.
- I understand that my referring physician may be informed of my participation in this research study.
- I agree that Dr. Kennedy’s research group may apply for and use patents relating to the research results, records and developments. I acknowledge that I will not derive any financial benefit from these patents and applications.
- I have read each page of this form.