University of British Columbia
Department of Psychiatry

Children's & Women's Health
Centre of British Columbia

Subject Information and Consent Form

Effect of genetic counselling on treatment adherence and illness management-related self-efficacy in serious mental illness.

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Sponsor: Pfizer Canada Inc.

Introduction: You are being invited to take part in this research study because you have, at some point in your life, received a diagnosis of schizophrenia, bipolar disorder, or schizoaffective disorder. Researchers are interested in better understanding the impact of genetic counselling for people who have mental illness; and in particular, how it might affect people's feelings about how they manage their illness.

Participation: Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

Background: Mental illnesses such as schizophrenia and bipolar disorder are common, and research shows that people who have these illnesses would like to better understand what caused their condition. Genetic counselling is a process that helps people to better understand how their illness developed. However, we know little about the effects of genetic counseling for people with mental illness.

What is the purpose of the study? In this study, we will explore how genetic counseling influences how people with mental illness feel about managing their condition.

Who can participate in the study? Individuals who are 19 years old or older and who have a psychiatric illness such as schizophrenia, bipolar disorder, or schizoaffective disorder can participate, as long as they are fluent in English and are not currently experiencing psychosis.

Who should not participate in the study? Individuals whose only experience of psychosis was attributed by doctors to the use of drugs.

What does the study involve? If you agree to take part in this study, it will involve 2 in person visits and filling out questionnaires at 2 later time points (about one month apart).

1st Appointment (1.5 to 2 hrs.): You will complete the interview and questionnaires described below. Also, you will be asked to complete a release of information form (this form asks for your permission for the researchers to access your medical record relating to your psychiatric diagnosis). The researcher will also ask you basic demographic questions such as your age, gender, employment, etc.

2nd Appointment (1 to 1.5 hrs.): You will be asked to come back about two weeks after the first appointment for a genetic counselling (GC) appointment. Immediately before the GC appointment, you will be asked to complete questionnaires (described below). Immediately after genetic counselling you will be asked to complete a questionnaire about your experience during genetic counseling session.

3rd and 4th Appointments (1 hr.): You will be asked to complete the questionnaires (described below) one and two months after the genetic counseling session at home either by phone with research assistant, online, or by mail (according to your personal preferences and available resources).

Genetic Counselling: You will meet with a genetic counsellor who will talk with you about the mental illness(es) in your family, and will describe for you exactly what is currently known about what causes the illness(es), including the role of genetics. The counsellor will take a detailed family history and will

discuss this with you. You will have the opportunity to ask questions throughout.

Interview: You will meet with a researcher who will ask about your mood. This will take approximately 45 minutes.

Questionnaires: You will be asked to complete questionnaires about your knowledge about the causes of mental illness, your illness management, and your mental health medications. This will take about 30 minutes.

What are my responsibilities? If you participate in the study, we ask that you refrain from taking any alcohol or street drugs in the 24-hour period prior to the study visit.

Possible harms and side effects of participating: It is possible that you may be upset by thinking and talking about your family or medical history at the time of interview, you can choose not to answer questions. The researchers will address your concerns and/or provide resources for support, as appropriate, should any issues arise.

What are the benefits of participating in this study? No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people with a similar illness. You may feel that learning more about the causes of mental illness, understanding more about the genetic contribution to mental illness, and having the opportunity to ask questions of an expert is a benefit. Additionally, you may consider it beneficial to have your family and medical history thoroughly reviewed by researchers who may be able to identify medical conditions running in your family. If this is the case, this will be discussed with you, and if you would like, a referral to the Department of Medical Genetics at BC Children and Women's Hospital can be arranged.

Confidentiality: Your confidentiality will be respected. Any information regarding your participation in this research study will not be disclosed to anyone outside the stated research team. You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study 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. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada, and the UBC Research Ethics Boards for the purpose of monitoring the research. However, no records that identify you by name or initials will be allowed to leave the Investigators' offices.

During visit 1, a computer led interview on your mood will be conducted by a researcher using the NetSCID Internet based software developed by TeleSage Inc. Your subject ID and information from the interview will be entered into the Internet software program and saved onto the database located in Chapel Hill, North Carolina in the United States of America. No identifying personal information will be entered into the database. All data is encrypted and will be stored on TeleSage's password-protected service bureau LAN, which is also firewall-protected, and not accessible via the internet. Following the interview, the data will be downloaded by the researcher who conducted the interview through a secure download using an https website and then stored on a password protected and encrypted database at the University of British Columbia. The de-identified data will remain on the TeleSage server indefinitely. TeleSage may use these de-identified data to improve the NetSCID program or in other research projects relating to the diagnosis of mental disorders. Data stored by TeleSage will not be used by anyone without the permission of the principal investigator of this research study.

Any study related data, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries *[for example, the Patriot Act in the United States]* dealing with protection of information may not be as strict as in Canada. However, all study related data that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your de-identified information, to organizations located outside of Canada, specifically TeleSage Inc. in Chapel Hill, North Carolina, USA.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor 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 doctor.

Remuneration/Compensation: You will receive $10.00 in return for the completion of the interview and questionnaires during the first two in-person visits and by mail after you completed the interview and questionnaires at home.

Contact for information about the study: If you have any questions or desire further information with respect to this study, you may contact Dr. Jehannine Austin or one of her associates at 604 875 2000 ext. 5943.

Contact for concerns about the rights of research subjects: If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or, if long distance, 1-877-822-8598 or send e-mail to RSIL@ors.ubc.ca.

Consent: Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without jeopardy to your participation in future studies.

Please check the following boxes before signing this form:

- ❑ I have read and understood the subject information and consent form.
- ❑ I have had sufficient time to consider the information provided and to ask for advice if necessary.
- ❑ I have had the opportunity 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 result will only be used for scientific objectives.
- ❑ I understand that my participation in this study is voluntary and 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 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
- ❑ I have read this form and I freely consent to participate in this study.
- ❑ I have been told that I will receive a dated and signed copy of this form.

_____	_____	_____
Printed name of Subject	Signature	Date
_____	_____	_____
Printed name of principal investigator Or designated representative	Signature	Date