SHORT TITLE OF PROJECT: GENETIC STUDY OF SCHIZOPHRENIA

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What is the Molecular Genetics of Schizophrenia Project?

This is the second phase of a research study that has been established at The Queensland Centre for Mental Health Research (QCMHR) The Park, Centre for Mental Health, Wacol, Brisbane. The purpose of this study is to find inherited factors (genes) that play a part in causing schizophrenia. To do this, we need the help of more than 600 individuals who have schizophrenia or related problems, and their families, and more than 600 individuals who do not have schizophrenia or related problems (controls, or comparison group) over the next four years. In collaboration with a number of US centres, extensive DNA analysis will be performed on the total number of approximately 4,500 affected individuals, their families, and controls. This study is funded by the National Institute of Mental Health (USA).

Why is the study important?

The cause of schizophrenia is unknown, but there is good evidence that genes play an important role. Genes are parts of cells. They are a code for the parts of your body and are made up of DNA. Genes come from parents. There are new methods for studying genes. Comparing the DNA from individuals who have schizophrenia with the DNA from individuals who do not may help to identify schizophrenia susceptibility genes. If genes related to schizophrenia can be found, then it may be possible to find better treatments that correct the basic causes of the illness, and identify factors that protect against the illness.

How are individuals contacted?

In accordance with strict rules for research studies, we have received permission from the relevant Heads of Department to work with staff members at clinics and hospitals. These staff members introduce the study to patients who may be suitable. The patient is asked for their permission for the researchers to contact them. If possible, the patient is then asked for permission to contact relatives. Controls are selected at random from the Commonwealth Electoral Roll.

What can I do to help?

You are invited to take part in the Molecular Genetics of Schizophrenia Project.

All participation is voluntary and confidential. It is important that you understand that your participation in this study must be voluntary. If you do not wish to take part you are under no obligation to do so.

The Study is divided into two sections.

Part 1 is the minimum requirement for participation. Participation in Part 2 is optional.

Part 1

We would like to speak with you about your life experiences and your observations about other relatives. The interview can be at your convenience. We can come to your home if you prefer, or provide your transport to and from the hospital. Most interviews last between 1-2 hours, and with your permission will be videotaped. The videotape will only be used by the research team for diagnostic and reliability purposes and will be destroyed after the study is completed. With your permission a 20 ml (4 tspns) blood sample will be collected, from which DNA will be extracted. The blood sample will be collected from a vein in your arm with a needle (venepuncture).

It may be necessary for the researchers to review your medical records.

We may need to contact you at a later date to obtain more information. We may need to contact your treating clinician or caseworker for further information.

Part 2

In the second part of the study, we will conduct a Neurocognitive Assessment, which involves a number of computerised and paper and pencil tasks. This tests for memory, attention and concentration and should take
approximately two hours. For the computer tests you will be asked to remember some things over a short period of time. For the paper and pencil tasks you will be asked to answer some questions.

**Is my information kept confidential?**
All the information you give us will be kept confidential. Only members of the clinical research team will know your name. We will keep your identity a secret by using a code number. If you agree to participate, you will be allocated a nine-digit, five-letter code. The blood sample will be labelled only with this code, and then sent to the Brisbane laboratory. The clinical information (interview, video and medical records) will be labelled only with this code and then securely stored at the Brisbane coordinating centre. The key to the code is held under lock at the Brisbane coordinating centre. Your information, cell lines and DNA will be sent to the USA labelled only with the code number. Personal information that could be used to identify you will not be given out to anyone. If you wish to leave the study the researchers will tell the repository to remove your mental health information and genetic material. The repository can use the code number to remove your mental health information and genetic material, without ever knowing your name or other personal information. By using this code number, the repository will tell scientists not to include your data in their research. These scientists will not know your name or other personal information we learn about you.

**Will it cost me anything to take part in the study?**
Participation in this project will not result in any extra medical and hospital costs to you. You will receive reimbursement for any expenses incurred during your involvement in this study. You will also receive a $20 Coles/Myer voucher for the interview, a $20 Coles/Myer voucher for the blood draw and a $20 Coles/Myer voucher for the neurocognitive assessment to compensate you for your time and any inconvenience.

**Can I change my mind and withdraw from the study?**
Participation in this study is entirely voluntary: you are in no way obliged to participate. If you do participate, you can withdraw at any time. If you decide not to participate in this study, or you withdraw from this study, you may do this without comment or penalty. It will not affect your current or future medical treatment in any way. If you decide to withdraw, all material collected from you will be destroyed within 48 hours of notification of intention to withdraw.

**What will happen to my blood sample?**
The blood sample you give will be sent to the Queensland Institute of Medical Research and will be used to create a cell line, which is living tissue. A small portion of the cell line, without any personal information, such as your name, will be sent to a repository in the United States, sponsored by the US National Institute of Mental Health (NIMH).

**Will my blood sample be used for future research?**
DNA will be taken from the cell line and used for scientific research now and in the future. Your DNA and cell line, as well as clinical data and other information that you provide will be stored in the repository. These data and DNA will be made available by NIMH to qualified scientists around the world to study schizophrenia, or other illnesses or traits. Any use of these materials would first need to be reviewed and approved by NIMH. These scientists may not be currently working on this project right now. Many research groups now, or may in the future, include investigators from private companies. Scientists who have access to your information and DNA may have formed a collaboration with a private company in order to study in detail (by using the latest available technology) DNA collected from families or individuals. You should understand that such companies have an economic interest in using the genetic information found from testing your DNA, along with DNA from other participants, for the eventual development of commercial products that may later help others by improving the diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Some of the investigators involved in the analysis of your DNA and information that you provide may get some financial benefit from this work. There are no plans to provide any compensation to you or your heirs should this occur.

We will also be conducting other tests on your blood sample to investigate the link between genes and schizophrenia. These will include immunology and glucose tests.

By consenting to participate in this study, you consent to the storage and later analysis and testing of your stored blood samples for the purposes noted above. Your DNA may be used indefinitely by scientists conducting ethically approved research on the genetics of schizophrenia and other illnesses. We will not reapproach you for further consent.
Will I be given the results of the study?
No individual results will be available because all analyses will be conducted on the combined sample. Therefore no information relevant your health, the health of your relatives or yet unborn children will be available. A summary of the outcomes will be sent to all participants at the completion of the study.
We intend to publish the results only in scientific journals. You or your family will in no way be identified by name in any publication.

Will I benefit from the study?
It will take years of work to find better answers for schizophrenia. This study will not provide any immediate benefits. We try to be helpful by answering questions about schizophrenia, and, if needed, by providing information about available treatment. Many patients and relatives find the interviews interesting, and enjoy being able to help the study.

Are there any risks?
There are some possible adverse effects or risks related to participation in this project which include:
(a) Very occasionally, talking about family illness can be upsetting. If by chance the interview causes distress in individual patients or family members, the interview will be terminated and support provided by the interviewer. If a subject indicates a potential for self-harm, the interviewer will report these responses immediately to the treating clinician.
(b) Complications associated with blood sampling are infrequent and minor, and include local bruising and inflammation of the vein used. Persons drawing blood have been trained in venipuncture techniques to minimize these complications.
(c) At present, the Policy on Genetic Testing of the Life Insurance Federation of Australia states that companies will not initiate any genetic tests on applicants for insurance. A copy of this document can be obtained from the researchers. However, there is a possibility that at some time in the future, once genes predisposing to schizophrenia have been identified, insurance companies might wish to genetically test people before issuing policies.

How do I get more information?
You should ask for any information you want. If you would like more information about the study or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the researchers or one of the doctors treating you. You should feel free to do this.

If you have any questions about the study at any time, feel free to contact the researchers at the Queensland Centre for Mental Health Research, The Park, Centre for Mental Health, Wacol. QLD 4076.

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Ethical Guidelines
This study has been approved by the West Moreton Health Service District Human Research Ethics Committee. If you have any complaints about the study you can contact Ms Nadia Beer at The WPH Office of Patients Friend Telephone 3271 8567 or the Ethics Officer, WMHSD Human Research Ethics Committee on 3271 8674 or 3835 9900 pager 72124. Email steve_lewis@qcmhr.uq.edu.au. All complaints will be treated in confidence, investigated fully and you will be informed of the outcome.

I have read and I understand the Information Sheet for volunteers taking part in the study designed to find inherited factors (genes) that play a part in causing schizophrenia. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

SIGNED ____________________________ DATE __________________

WITNESS __________________________ DATE __________________