Participant Information Sheet

Title	***Proteins of the Immune System in Psychosis***
Short Title	PIPs
Protocol Number	HREC/51194/MH-2019
HREC ID number	2019.067
Principal Researchers	Dr Vanessa Cropley, A/Prof Andrew Zalesky, Prof. Christos Pantelis, Prof. Dennis Velakoulis, A/Prof Cynthia Shannon Wiekert, Dr Franz-Markus Leweke,
Associate Researchers	Prof. Susan Rossell, Dr Wei Lin Toh, Dr Eleni Ganella, Dr Mahesh Jayaram, Dr Ajit Selvendra, Alicia Stevens
Students	Megan Thomas
Location	Melbourne Health, Melbourne Neuropsychiatry Centre, University of Melbourne, St. Vincent's Hospital

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Part 1 What does my participation in the project involve?

1. Introduction

You are invited to take part in this research project as you have expressed interest from one of our advertisements. The research project aims to investigate if there are changes in the brain that may explain why a person develops psychosis.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. You may ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a carer, relative, friend or healthcare worker.

Participation in this research is **voluntary**. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to have the tests that are described;
- consent to the use of your personal and health information as described.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. What is the purpose of this research?

This project aims to investigate if there are changes in the brain that may explain why a person develops schizophrenia. To do this, we will be investigating the role of the immune system in people with recently diagnosed schizophrenia, and people without schizophrenia, to see if the immune system affects how the brain develops. The immune system is made up of organs, cells and proteins and is the body's defence against infections which help keep us healthy. This research study wants to see if a specific protein in the immune system is increased in people who experience schizophrenia, especially people who have recently been diagnosed.

We will perform Magnetic Resonance Imaging (MRI) to take pictures of your brain. MRIs have been used for a long time and you may have had one of these before. The MRI scan allows us to see what your brain looks like and to see whether the structure of the brain is related to the immune system protein we are interested in. We are also asking participants to take part in a fasting blood sample (to measure the immune proteins), a clinical interview and to complete some tests of memory and attention.

This study has been initiated by Doctor Vanessa Cropley, The University of Melbourne. The study involves researchers from a number of organisations working in collaboration. The study has been funded by a National Health and Medical Research Council Project Grant.

The results of this research will be used by Megan Thomas to obtain a Doctor of Philosophy – Medicine, Dentistry and Health Sciences.

3. What does participation in this research involve?

If you agree to take part in this research project the following procedures will occur at the baseline assessment (see the following pages for more details):

i. Online at home surveys (30 minutes)
ii. A clinical assessment interview (30 minutes);
iii. Cognitive assessments of brain function (2 hours);
iv. Collection of a fasting blood sample (15 minutes); and
v. A Magnetic Resonance Imaging (MRI) brain scan (1.5 hours).

In total, the baseline study procedures described above will take roughly 4-5 hours and will be completed over 1-2 days.

We are also asking for an 18-month follow up assessment, where the following procedures will occur:

i. A brief clinical assessment interview (15 minutes);
ii. Cognitive assessments of brain function (2 hours);

In total, the 18-month follow up assessment will take roughly 2-3 hours and will be completed over 1 day.

You are asked to avoid taking alcohol or drugs prior to each session to ensure that these substances do not influence the study results.

i) Online at home surveys

You will be emailed some online self-report questionnaires that you will be asked to complete at home, prior to attending your first session. These will collect information about yourself, such as information about your experiences in childhood, schooling, employment and family.

ii) Clinical assessment interview

You will be asked to attend one session with a researcher. During this meeting, you will be asked to give information about yourself, such as information about your medical history, drug and alcohol use, and about your moods, thoughts and experiences.

iii) Cognitive assessment interview

During these assessments, you will be asked to complete some tasks that measure your brain function. These will test things like learning, memory and attention, and will be done with pen and paper. You will be voice-recorded during some of these tasks that require you to respond rapidly, and where it may be difficult for the researcher to manually record your responses in real-time. We will use the voice-recordings to assess subtleties in speech, which could reflect your underlying thinking or emotional patterns.

iv) Blood sample collection

We will ask you to provide a fasting blood sample. A fasting sample means that you cannot eat food from about 10pm the night before until the sample has been collected. The blood sample will be taken at the Pathology Centre at the Royal Melbourne Hospital. This department has no other involvement in the study. On the morning of the blood collection, we ask that you do not eat food or consume caffeine from the time you wake up until the blood test is completed. We encourage you to drink water before the blood collection. About 50 ml (2 tablespoons) of blood will be collected in several tubes by someone trained in collecting blood. The blood sample will be taken for the measurement of specific immune system proteins that we are interested in for the research question. Some blood will also be tested to see if the blood clots normally. You will be offered breakfast after the blood sample has been collected.

v) Brain MRI scan

You will be asked to have a MRI scan of your brain. This will be performed at the Royal Children's Hospital. The MRI scan will take about 1 hour, and will include a 30-minute break half-way through, meaning that the session will take a total time of about 1.5 hours.

MRI uses electromagnetic fields (radio waves), but no radiation, to obtain images of body organs and tissues. In this case, the scan will be used to take pictures of the anatomy, or structure, of your brain.

Before the MRI scan you will be asked questions to make sure it is safe for you to have the MRI. You must not have any metal object on or in your body, for example, brain aneurysm clips or a pacemaker. You will be asked to remove any magnetic objects (such as coins, watches, jewellery). We will ask you to lie on a table inside the MRI scanner. It is important that you keep very still during the scanning. When you lie on the table we will make sure you are in a comfortable position so you can keep still. The scanner is noisy and we can give you some earphones to reduce the noise. The noise level will not affect your hearing. Inside the MRI scanner you will be able to close your eyes and relax, or watch a movie of your choice on a small screen located behind the scanner.

We will send you a picture of your brain in the weeks following the MRI scan if you would like.

4. Reimbursement

There are no costs associated with participating in this research project, nor will you be paid. You will be reimbursed for your time involved in completing the tasks listed above. For the baseline assessment, after completion of each task, you will be reimbursed $20 for the online at home surveys, $20 for the clinical interview, $20 for the cognitive assessments, $20 for the blood draw and $40 for the MRI scan. For the 18-month follow up assessment, after completion of each task you will be reimbursed $20 for the clinical interview and $20 for the cognitive assessments. Therefore, there is a maximum of $120 reimbursement for taking part in the baseline assessment and $40 for the 18-month follow-up. This is to cover costs that

happen because of participating in this research project, including transportation to and from testing sessions and parking. You will be given this reimbursement in the form of an e-Gift card of your choosing.

5. Other relevant information about the research project

This study aims to recruit 140 participants: 40 individuals with recently diagnosed schizophrenia (within the first 5 years) and 100 control participants with no history of a psychotic disorder or current psychiatric condition. All individuals who have schizophrenia will be registered with a mental health service and all controls will be recruited from the general community.

You have been invited to participate in this study because you are between the age of 18 and 40 years and represent the general population. You will need to meet certain eligibility criteria to participate in this study. The eligibility criteria will be discussed with you by a study doctor or other members of the research team.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with The University of Melbourne.

7. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. Your involvement will help us improve our understanding of the onset of psychotic disorders and ways of providing treatment for young people at risk of psychosis.

8. What are the possible risks and disadvantages of taking part?

Blood collection: Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

The brain MRI scan: An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the brain. The pictures taken by the machine are called MRI scans. Electromagnetic radiation is not the same as ionizing radiation used, for example, in X-rays, therefore MRI does not involve radiation.

We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your brain. It is very important that you keep very still during the scanning. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert the staff by pressing on a call button.

There are no long-term risks associated with MRI scans as used in this research project. MRI is considered to be safe when performed at a center with appropriate procedures. However, the MRI scanner has a strong magnet and the magnetic attraction for some metal objects can pose a safety risk. It is important that metal objects are not taken into the scanner room.

Radiography staff will thoroughly examine you to confirm your suitability for the scan. You must tell us if you have metal implanted in your body, such as a pacemaker, metal pins or metal piercings.

Questionnaires and interview: Some of the questions we will ask cover sensitive topics and could therefore cause distress. Our research team has lots of experience with the questionnaires and the interview used in this study. However, please note that you do not have to answer any questions you do not want to. If you feel distressed after completing the interview or the questionnaires, you should let someone from the

research team know. You can also contact the principal investigators – their numbers are listed in Section (19) of this form.

Other possible risks of study participation: If at any time you feel distressed throughout the study, you may suspend your participation or withdraw from the study. You can also contact the Principal Investigators if there are any concerns – their numbers are listed in Section (19) of this form. Researchers are able to arrange for counselling or other appropriate support if it is required. Any counselling or support will be provided by staff who are not members of the research team.

There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any news or unusual symptoms that you experience.

9. What happens if something abnormal is found in my MRI scan?

This study is for research purposes only and is not a clinical examination. This means the brain scans are not designed to diagnose or help manage or treat a medical condition.

Very occasionally (in approximately 2% of cases) MRI images reveal unexpected things. Most of these findings have no negative implications for health. However, in some cases, the unexpected findings may represent a genuine health risk. Your brain scans will be reviewed by a study doctor as routine procedure.

If an unexpected finding is observed, you will be immediately contacted by our research team, who will ensure that you receive appropriate follow-up. This will include talking with your doctor, and if appropriate, an out-patient neurology clinic appointment. You should be aware that because our pictures are taken for a specific research purpose, not all abnormalities that might be detected by other MRI scans are necessarily seen. Please be aware that these findings may reflect normal differences in brain anatomy; however, as the MRI scans that we are conducting are not diagnostic we cannot make any judgement about such findings. Therefore, we will inform you of the finding and advise you about further investigation you may wish to obtain. If you do not want to be made aware of this incidental finding, you should choose not to enter into the study.

Although finding a significant abnormality is extremely unlikely, you should be aware that if an abnormality is found and you are told about it, this information might have consequences for you. Knowing about an abnormality may affect your ability to work in certain professions, obtain life or health insurance and interfere with other aspects of daily living. However, the discovery of a health risk may also help get you treatment. Please take the time to consider the advantages and disadvantages of discovery of a health risk before consenting to take part in this research project. Please let us know if you have any questions or would like anything clarified.

10. What if new information arises during the project?

Sometimes during the course of a research project, new information becomes available about the risks and benefits of the project may become known to the researchers. If this happens, the study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

11. Can I have other treatments during this research project?

Yes, you can continue to receive any treatment you are presently having. However, it is important to tell the research staff about any treatments or medications you may be taking. This includes over-the-counter

medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also inform us about any changes to these during your participation in the research.

12. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

If you decide to withdraw your consent during this research project the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want this to happen, you should choose not to enter into the study.

13. What will happen when my participation in this research project ends?

In the future, we may follow-up participants in this study to see how specific functions (e.g. cognition or brain structure) have changed over time. A follow-up study will only take place following ethics approval from a relevant Human Research Ethics Committee. You will be asked to indicate whether you would like to be contacted about any follow-up studies in the future.

You will receive updates, via an email newsletter, about the progress of the study throughout the duration of the research project. Upon request, a short summary of the results of the study will be sent out to you once the study is complete. To obtain this please contact one of the investigators listed in Section (19).

14. What happens if I am injured as a result of participating in this research project?

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

Part 2 How is the research project being conducted?

15. What will happen to information about me?

By signing the consent form, you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential, stored securely, and will only be used for the purposes stated in this document. The information that you give to the study will only be disclosed with your permission, except as required by law. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. You may choose to have a support person, such as your carer, present during these discussions.

Your data will be coded with a unique identifier that we will allocate as soon as you consent to participate in the study. This means that we will remove your name and other identifying details from your data. Only the researchers directly involved in the current project will have access to the information that links your personal data with your unique identification number, and only if it is necessary to do so.

Consent forms containing participants' names and any contact information will be stored in a locked cabinet at the Melbourne Neuropsychiatry Centre. Pen and paper research data associated with this study will be stored in a locked cabinet separate from the consent forms. Electronic research data will be stored on password-protected computers at the Melbourne Neuropsychiatry Centre. MRI images will be stored on a

secure password-protected server hosted by the University of Melbourne, accessible only to the investigators.

Information about you will be obtained from your medical record, and may be obtained from other health services such as from your local doctor or other hospitals, for the purposes of this research. By signing this consent form, you agree to the research team accessing health records if they are relevant to your participation. Your participation in this study will be added to your medical record.

i) What will happen to my blood test samples?

By consenting to take part in this research project, you also consent to the collection, storage and use of tissue samples as specified below.

After your blood samples are collected they will be stored in a freezer at the Australian Imaging, Biomarker & Lifestyle Study of Ageing (AIBL) laboratory at the Mental Health Research Institute (MHRI) in Melbourne Victoria. This is a secure facility and only the key investigators in the study will have access to the use of your samples. Your blood samples and any paperwork accompanying the samples will be labelled with a unique study code, not your name, address or hospital number. The blood samples will be stored until they are analysed for specific markers at a later date.

With your consent, some of the blood collected will be stored for future use in research studies in the future. This is an **optional** part of the study. If you do not want your blood samples stored for future studies, you don't have to. Furthermore, you can consent to the storage and use of your blood sample for future studies, and later change your mind. If you consent to the long-term storage and use of your samples the samples will be kept indefinitely in the Melbourne Neuropsychiatry Centre Research Tissue Bank. Please see Section 15(ii) below for further information about the registration of your samples into this Tissue Bank. As outlined above, these samples will be stored in locked freezers at the MHRI. The stored blood samples may be used to examine particular genes or proteins that are involved in neuropsychiatric disorders, inflammation or immune function. Genes are inherited from our parents and provide the information that determines our personal attributes such as hair and eye colour. Future studies using your stored blood samples will only take place following ethics approval from a relevant Human Research Ethics Committee. No identifiable information (i.e. name, address or date of birth) will be provided to researchers, ensuring the privacy and confidentiality of your data. You will be asked to indicate your choice for the collection, storage and use of your blood sample for this future research in the consent section of this document.

The blood samples collected for this specific research and future research are for research purposes only and not for any commercial gain. They will not produce the type of results that will have any useful meaning that would affect your health or treatment. The type of genetic testing that may be done on your stored blood samples in future studies is not testing that would result in information about your future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project. Therefore, you will not be provided with the results of the tests or of any genetic testing conducted in future studies. If the investigators become aware that any analyses have implications for you or your family members, you will be made aware of the information. In general, we will not give you any individual results from the study of the samples you give us.

ii) Registration of data into the Melbourne Neuropsychiatry Centre Research Databank and Tissue Bank

The Melbourne Neuropsychiatry Centre (MNC) plans to assemble a database of in excess of 5,000 brain scans and associated clinical research data and biological material (i.e. blood). The researchers at MNC have been actively conducting research projects in mental health and neurosciences since 1994 and have collected clinical research data and brain imaging data in over 3,000 research participants.

With your consent, we would like to keep the information and biological samples from this project indefinitely and store it in the MNC Research Databank and Tissue Bank. Please read the separate information sheet regarding the MNC Research Databank and Tissue Bank before consenting to your data being stored in a particular way. The MNC Research Databank and Tissue Bank has received Melbourne Health Human Research & Ethics Committee approval (MHREC: 2009.607, Melbourne Neuropsychiatry Centre (MNC) Research Databank and Tissue Bank, Professor Christos Pantelis). We would like to keep your information and your blood samples in this Databank/Tissue Bank indefinitely as there is a possibility that it may be re-used at a later stage to address future research questions. However, if you do not want your information to be stored indefinitely for this purpose then you have the option of your information being destroyed after the minimum of 7 years following completion of the study. You will be asked to indicate your choice for the registration of your data and biological samples into the MNC Research Databank/Tissue Bank in the consent section of this document.

iii) Registration of data for future use

Some scientific journals are now asking to provide de-identified data for future use by scientists around the world. As mentioned above, the de-identified data is data that does not include any information that could identify you (i.e. name or initials). Sociodemographic (e.g., age, gender), neurocognitive (e.g., performance on cognitive tasks), physiological (e.g., weight) and imaging data may be coded and uploaded to secure servers. Please indicate on the consent form whether you are happy for your de-identified data to be stored on secure servers and used in future research collaborations.

At the end of this form, you will have the opportunity to consent to allowing information collected about you to be used for future research. Consenting to allow the use of your data for future research is optional, so you do not have to consent to it if you don't want to. It is unlikely that these studies will have a direct benefit to you, and you will not receive results from these future research project. Any future research projects wanting to use your data will have to be reviewed and approved by a recognized Human Research Ethics Committee. Any future research will be conducted by the University of Melbourne and may involve collaborations with other researchers in the mental health field.

16. How can I access my information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named in Section 19 if you would like to access your information.

17. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

For further information on who to contact please see Section (19) below.

18. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Melbourne Health HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems, which may be related to your involvement in the project (for example, any side effects), you can contact any of the following people:

Contact persons:

Name	Dr Vanessa Cropley
Position	Principal Investigator
Telephone	(03) 8344 1876
Email	vcropley@unimelb.edu.au

Name	Professor Christos Pantelis
Position	Associate Investigator
Telephone	(03) 8395 8118
Email	cpant@unimelb.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person:

Name	Dr Vanessa Cropley
Position	Principal Investigator
Telephone	(03) 8344 1876
Email	vcropley@unimelb.edu.au

The Melbourne Health Human Research Ethics Committee (HREC) has approved this study. If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details:

Reviewing HREC Name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.org.au

Local HREC Office contact (Single Site - Research Governance Officer):

Name	Director Research Governance and Ethics
Position	Complaints Manager
Telephone	(03) 9342 8530
Email	Research@mh.org.au

Consent Form

Title	***Proteins of the Immune System in Psychosis***
Short Title	PIPs
Protocol Number	HREC/51194/MH-2019
HREC ID number	2019.067
Principal Researchers	Dr Vanessa Cropley, A/Prof Andrew Zalesky, Prof. Christos Pantelis, Prof. Dennis Velakoulis, A/Prof Cynthia Shannon Wiekert, Dr Franz-Markus Leweke,
Associate Researchers	Prof. Susan Rossell, Dr Wei Lin Toh, Dr Eleni Ganella, Dr Mahesh Jayaram, Dr Ajit Selvendra, Alicia Stevens
Students	Megan Thomas
Location	Melbourne Health, Melbourne Neuropsychiatry Centre, University of Melbourne, St. Vincent's Hospital

Declaration by Participant

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had the opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I understand that I will be voice-recorded during some components of the study
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the study researchers concerning my previous treatment that is needed for this project. I understand that such information will remain confidential.

Optional consent items:

I consent to researchers contacting me in the future to participate in a follow-up study related to this study. I understand I am under no obligation to participate in follow-up studies:

☐ Consent to contact for follow up studies Initial: _____ Date: _____ / _____ / _____

I consent to the researchers contacting me in the future regarding involvement in other research. I understand I am under no obligation to participate in future research:

☐ Consent to contact for future research studies Initial: _____ Date: _____ / _____ / _____

Registration of research data to the MNC Research Databank and Tissue Bank:

I consent to allow my brain scan and associated clinical research data to be included in the MNC Research Databank and future research as explained in this document:

☐ Consent to brain scan to go into MNC Research Databank Initial: _____ Date: _____ / _____ / _____

I consent to allow my blood to be securely stored and included in the MNC Research Tissue Bank and future research as explained in this document:

☐ Consent to blood storage at MNC Research Tissue Bank and future research Initial: _____ Date: _____ / _____ / _____

Declaration of Participant for access to de-identified data:

By signing this consent section, I acknowledge that anonymous sociodemographic, neurocognitive, physiological and imagining data (as outlined on Page 7) may be stored in secure servers accessible (on request) by scientists around the world to facilitate further research:

☐ Consent to facilitate future research Initial: _____ Date: _____ / _____ / _____

Name of Participant (please print) _____

Signature _____ Date: _____ / _____ / _____

Name of Witness to Participant's Signature[†] (please print) _____

Signature _____ Date: _____ / _____ / _____

[†] Witness required when participant cannot read this document for themselves except where an interpreter is used.

Declaration by Principal, Associate Investigator or Research Assistant:

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Principal, Associate Investigator

or Research Assistant (please print) _____

Signature _____ Date: _____ / _____ / _____

Time (00:00 format) of consent: _____

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

Title	***Proteins of the Immune System in Psychosis***
Short Title	PIPs
Protocol Number	HREC/51194/MH-2019
HREC ID number	2019.067
Principal Researchers	Dr Vanessa Cropley, A/Prof Andrew Zalesky, Prof. Christos Pantelis, Prof. Dennis Velakoulis, A/Prof Cynthia Shannon Wiekert, Dr Franz-Markus Leweke,
Associate Researchers	Prof. Susan Rossell, Dr Wei Lin Toh, Dr Eleni Ganella, Dr Mahesh Jayaram, Dr Ajit Selvendra, Alicia Stevens
Students	Megan Thomas
Location	Melbourne Health, Melbourne Neuropsychiatry Centre, University of Melbourne, St. Vincent's Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationship with Melbourne Health, Melbourne Neuropsychiatry Centre/ University of Melbourne or St. Vincent's Hospital.

Name of Participant (please print) _____
Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher[†] (please print) _____

Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning withdrawal from the research project.