

# **Participant Information Sheet/Consent Form**

## **Control - Adult Providing Own Consent**

### **Melbourne Health**

<b>Title</b>	Markers in Neuropsychiatric Disorders: investigating biomarkers and clinical markers in neuropsychiatric, neurological and neurodegenerative disorders
<b>Short Title</b>	MiND
<b>Protocol Number</b>	2020.142
<b>Project Sponsor</b>	The Royal Melbourne Hospital
<b>Principal Investigators</b>	Professor Dennis Velakoulis, Dr Dhamidhu Eratne and the Melbourne Health MiND Study Group
<b>Location</b>	The Royal Melbourne Hospital

## **Part 1: What does my participation involve?**

### **1. Introduction**

You are invited to take part in this research project, Markers in Neuropsychiatric Disorders (MiND). This is because you (and your doctor) have identified no symptoms or signs of neurological or neuropsychiatric illnesses. You are therefore being asked to take part as a “control”, so that your samples and clinical information can be compared to people with neurological and neuropsychiatric diseases, to help us understand these diseases better.

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

Please read this information carefully. 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 relative, friend or local doctor.

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 or not you take part.

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 the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

### **2. What is the purpose of this research?**

The brain and nervous system are extremely complicated. We still have a long way to go to improving our understanding of illnesses of the brain and nervous system. Even after seeing many doctors and having lots of tests, many people still struggle with uncertainty, wrong diagnosis, and wrong treatments, sometimes over many years.

Research we and others have done, has started to show that measuring levels of proteins or “biomarkers”, such as one called ‘neurofilament light’, can significantly improve our understanding of these illnesses, for example improving our ability to diagnose early, quickly and accurately.

This research study aims to study how well the biomarker neurofilament light can improve early, accurate diagnosis, to fill in many gaps in our understanding, and improve clinical care and outcomes for patients and their families.

By collecting and storing blood to measure neurofilament light biomarker levels now, and using the remaining sample for the future when new biomarkers are discovered, and linking these levels with clinical information, we will be able to significantly improve our understanding of these diseases and how neurofilament light and other biomarkers can help to better diagnose and potentially prevent and treat them.

All samples you provide, and all your associated health information, are stored securely, and are used only for medical and health-related research projects.

Our research study could lead to important outcomes for patients and their families. For example, our study could lead to a simple blood test that even a general practitioner can do, right at the beginning, to diagnose and guide further tests (or not), that would be a significant improvement on how we do things currently, with positive impacts for patients and their families.

### **3. What does participation in this research involve?**

Your participation is completely voluntary, and will only start after you have been given information on the study, have been able to ask all the questions you want, and after understanding the study and wish to continue, you sign the consent form to document this. You will be given the opportunity to discuss any questions with the research coordinator or one of the investigators. Your medical care will happen as normal.

#### **By agreeing to participate, you are agreeing to:**

- 1. Sign the consent form**
- 2. Provide a blood sample**, similar to a standard clinical blood test and should take less than 15 minutes, for testing of the biomarker neurofilament light
- Permission for the study to **collect relevant information from your standard, routine medical care**, from your medical records and treating doctors, which will allow us to properly understand and interpret biomarker levels
- Complete optional additional questionnaires and surveys. This will help us have as much detailed information as possible to properly understand the neurofilament light biomarker levels

Where possible we will undertake study activities at your regular medical appointments. This may not always be possible, therefore, to reduce inconvenience for you, we will provide you with a range of options, for example: to complete consent, questionnaires and surveys over the telephone or online, and to provide a blood sample at your local community pathology service. If you are providing samples for tests as part of your standard clinical care, we will try to use remaining samples for this research study, in order to reduce any additional procedures for you.

If you agree to participate in the study you are also giving permission for the study to collect relevant information from your medical records and treating doctors and link this information with State and Commonwealth databases (e.g. Medicare Benefit Schedule (MBS), Pharmaceutical Benefits Scheme (PBS) etc.) and clinical registries. Linking this data brings together information that relates to you from different data sources. This helps researchers obtain important clinical information and check the accuracy of the data collected, and determine the potential healthcare savings of neurofilament light. You will be asked to sign an

additional consent form specific to the release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of this research study.

The health information collected from medical records from your routine clinical care could include information such as personal information (e.g. education, employment status, lifestyle factors), details about your diagnosis and symptoms, pathology results, medical history and family history, investigations like MRI (magnetic resonance imaging) and PET (brain) scans, and neuropsychological assessments that may have been done as part of routine clinical care.

By participating in this study, you are providing access to your remaining samples and data that are an extremely valuable resource for this study, and future health and medical research that will only occur with ethics approval from a human research ethics committee (HREC).

The Consent form also gives you the option to consent to be contacted by researchers about future studies.

You may also choose to:

- Provide a second blood sample about two years later. This will allow us to understand how levels of neurofilament light biomarker protein change over time, what that means and how it can be used to improve medical care

There are no costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit, up to a maximum of AUD\$100.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research study.

#### **4. Do I have to do anything differently? Can I have other treatments during this research project?**

Participation in this study does *not* change anything else in your healthcare and standard clinical treatment. There are no lifestyle or dietary restrictions, or other changes you need to make just because you are participating in this study. You should follow your usual clinical treatment with and advice from your treating doctors and other healthcare professionals, and continue to take your usual, regular medications. You can have other treatments and participate in other research projects.

#### **5. Other relevant information about the research project**

- This research study has the potential to recruit at least 150 participants per year
- In order for a study like this to be successful, many collaborations with medical researchers from a number of organisations with expertise and equipment and technology is required
- It is possible that your samples *may* be used for genetic research in the future
  - o Genes are made of DNA, the chemical structure that carries your genetic information and is like your body's "instruction manual" that determines many human characteristics such as the colour of your eyes or hair
  - o Researchers study genes in order to understand why some people have a certain symptoms or conditions, and why some people do not. Understanding a person's genes also may be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect and others do not
  - o As this is a study of research (not clinical) tests, any genetic research will be: research-focused and focused on genes/gene changes that we do not know

enough about yet to use for any clinical purposes. Your data will only be used for pooling data from lots of participants and only for research purposes, will **not** identify you or your family personally in and scientific publications, will **not** be put in your medical records, and will **not** be shared with you or your family. Like all other data, this data will be stored securely. As you, your family, or your treating doctors will not receive any of this genetic research information, this means that any genetic research will **not** have any insurance or employment or hereditary implications for you or your family

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

Participation in any research study is voluntary. If you do not wish to take part, you do not 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 Royal Melbourne Hospital.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

## **7. What are the possible benefits of taking part?**

It is unlikely that you will directly benefit by taking part in this research study, because the most important health benefits will be realised years from now. However, your participation will contribute and benefit the advancement of scientific knowledge, our understanding of diseases, and help future generations.

## **8. What are the possible risks and discomforts of taking part?**

This research study does not involve any interventional treatment. You may have none, some or all of the effects listed below. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

### **- Blood collection:**

- The blood test you will have in this study will follow the same procedure as a blood test you would have in your standard clinical care. The blood test will be performed by a highly trained and experienced staff member
- The risks with standard blood tests are minimal when done by a qualified person with appropriate technique. There is a small risk of discomfort, bruising, and infection (extremely rare) at the site of the needle puncture. Some people can feel dizzy or faint after they give blood. All of these can be easily treated

### **- Unplanned or 'incidental findings':**

- During research, it is possible that information is discovered that has serious and significant health implications for you. It may also reveal something about you that is unrelated to your original disease. This information is known as 'incidental findings'
- As this study is focused on research tests (not clinical tests), it is very unlikely that there will be any of these incidental findings. However, in the unlikely event that something potentially clinically relevant is identified, this will be urgently reviewed by the senior study doctors. Only findings that meet the following criteria will be fed back urgently to your treating doctor, to then discuss and return the findings to you:
  - significant (such as one that indicates a life-threatening condition)

- and/or
  - clinically actionable (for which there are specific established treatments) and
  - confirmed (that has been checked by senior study doctors, and confirmed as accurate and/or valid, as far as reasonably possible in a research context)
- **Other distress or discomfort:**
  - Any interaction that involves discussion or assessment of medical symptoms, particularly neurological, neurocognitive and neuropsychiatric, can potentially cause discomfort or distress. This also applies to any incidental findings. All study staff that interact with you have training and expertise with people with neurological or neuropsychiatric symptoms. Distress or discomfort with any part of the research study will be promptly and sensitively responded to by study staff. The study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge
- In the event that you suffer an injury as a result of participating in this study, hospital care and treatment will be provided by the public health service at no extra cost to you

## **9. What if I change my mind and don't want to participate?**

Even after your samples and health information have been collected, you are free to withdraw your consent at any time without having to give a reason. Withdrawing your consent to participate will not affect your medical treatment in any way. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers or your doctor, or Royal Melbourne Hospital. If you choose to withdraw, please contact the study staff (contact details below).

You may choose to withdraw from future sample and data collection while giving the study permission to keep the samples and information about you that have already been collected. You may also give the study permission to collect relevant follow-up information from your medical records for use in research and analysis. However, you will not be personally contacted by the study from then on. Should you choose to fully withdraw your consent, the study will discard your stored samples and associated personal and clinical information. However, if some or all of your samples have already been used or provided to a research project, it will not be possible to retrieve these samples.

Also, research that has been published cannot be deleted or discarded, but you will not be able to be identified in any way. All information used in research publications will be a collation of results of all study participants and/or will be in a coded format where individual names, addresses or other identifiers are not disclosed.

## **10. Could this research project be stopped unexpectedly?**

This research study is an ongoing study, and we do not anticipate any scenario in which this research would be stopped unexpectedly. However, in the unlikely event that it is stopped unexpectedly, you will be notified immediately and made aware of how your data will be stored and/or destroyed as required by the research and ethics departments.

## **11. What happens when the research project ends?**

This research study aims to provide significant research findings on an ongoing, indefinite basis. We want to be able to share summaries of these findings and the successes of the study, and your participation, with you. However, research of our kind can take a long time, sometimes

even years, to collect, analyse, finalise and publish. Findings will be published in scientific journals, on the study and Royal Melbourne Hospital websites, and shared with community organisations.

## **Part 2: How is the research project being conducted?**

### **12. What will happen to information about me?**

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal and medical information about you for the research project. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project, and critical for the study's success. Information about your participation in this research project may be recorded in your health records. Any information obtained in connection with this research project that can identify you will remain confidential.

All information will be stored on a secure, password protected database specifically designed for research, and housed at Melbourne Health/Royal Melbourne Hospital, and only accessible by study researchers. Any information recorded in paper form for this research will be kept in a locked filing cabinet in the senior study doctor's office at Neuropsychiatry, Royal Melbourne Hospital, that only researchers have access to.

The results of this study will be published and/or presented in a variety of forums, such as in scientific journals and at scientific meetings. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research study and for future research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

### **13. What will happen to my test samples?**

The blood samples collected from you will be labelled with a unique study code, and will be stored in freezers at a biobank such as the Florey Institute for Neuroscience, Parkville, Victoria.

Samples will be analysed for neurofilament light. In order to facilitate research on biomarkers that haven't even been discovered yet and maximise the benefits of this ongoing research study, your remaining samples will be stored indefinitely and used for any future unknown, unspecified medical research.

Your samples may be shared with study researchers in Australia and overseas in order to achieve the aims of this research study. If your samples are shared with study researchers outside of Melbourne Health, your samples will be sent in a coded manner. Any identifiable, personal information (such as name, contact details, etc.) will **not** be disclosed to them. Your samples will only be used for research purposes. No research will take place using your samples and information unless that research is first reviewed and approved by a properly constituted Human Research Ethics Committee, which will determine whether the benefits of the research outweigh the cost to you and your privacy.

Your samples will be re-identifiable, so that data from samples (such as biomarker levels) can be linked with your clinical information, which is crucial to properly understanding the biomarker levels, and the success of this study. Also, in the unlikely event of an incidental finding, study staff can de-code your sample (i.e. re-identify you) if necessary. Your privacy is paramount; only study staff will have access to the re-identifiable information, which is kept in a secure, password protected, research database.

It is possible that our research might result in medications or tests that are produced and marketed by private organisations. This study may or may not benefit from any of the revenue that such research may produce. If the research does lead to discoveries that are of commercial value to the researchers and their institutions, there will be no financial benefit to you or your family. If this study were to benefit from any discoveries, any funds so derived would be used for future research.

#### **14. Who is organising and funding the research?**

This research project is being conducted by Dr Dhamidhu Eratne and Professor Dennis Velakoulis. It is funded by the Australian National Health and Medical Research Council (NHMRC) and Medical Research Future Fund (MRFF).

#### **15. 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 reviewed and approved by the HREC of Melbourne Health. 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.

#### **16. 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 the principal study doctor on 03 9342 8750 or any of the following people:

##### **Clinical contact person**

Name	Professor Dennis Velakoulis or Dr Dhamidhu Eratne
Position	Consultant Neuropsychiatrist
Telephone	03 9342 8750
Email	Dennis.velakoulis@mh.org.au or Dhamidhu.eratne@mh.org.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	Director Research Governance and Ethics
Position	Complaints manager
Telephone	9342 8530
Email	research@mh.org.au

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**

Name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone & email	03 9342 8530 & research@mh.org.au

## Consent Form – Control

<b>Title</b>	Markers in Neuropsychiatric Disorders: investigating biomarkers and clinical markers in neuropsychiatric, neurological and neurodegenerative disorders
<b>Short Title</b>	MiND
<b>Protocol Number</b>	2020.142
<b>Project Sponsor</b>	The Royal Melbourne Hospital
<b>Principal Investigators</b>	Professor Dennis Velakoulis, Dr Dhamidhu Eratne and the Melbourne Health MiND Study Group
<b>Location</b>	Melbourne Health

### **Consent Agreement**

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 an 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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Melbourne Health concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

<b><i>Optional parts of the research project (please initial under your preferred response)</i></b>	<b>Yes</b>	<b>No</b>
I give consent to be contacted by researchers about future studies	<input type="checkbox"/>	<input type="checkbox"/>

### **Declaration by Participant**

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

<p><i>Declaration – only for participants unable to read the information and consent form</i></p> Witness to the informed consent process* Name (please print) _____ Signature _____ Date _____ <small>*Witness is <u>not</u> to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.</small>
---

### **Declaration by Study Doctor/Researcher**

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 Study Doctor/ Researcher (please print) _____  Signature _____ Date _____
--

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



## Form for Withdrawal of Participation – *Control*

<b>Title</b>	Markers in Neuropsychiatric Disorders – investigating biomarkers and clinical markers in neuropsychiatric, neurological and neurodegenerative disorders
<b>Short Title</b>	MiND
<b>Protocol Number</b>	2020.142
<b>Project Sponsor</b>	The Royal Melbourne Hospital
<b>Principal Investigators</b>	Professor Dennis Velakoulis, Dr Dhamidhu Eratne and the Melbourne Health MiND Study Group
<b>Location</b>	Melbourne Health

### **Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Melbourne Health.

<b><i>Options for withdrawing (please initial under your preferred response)</i></b>	<b>Yes</b>	<b>No</b>
1) I wish to withdraw but give researchers the permission to keep my samples and my personal and health information that has already been collected and to use them for future ethically approved research		
2) I wish to withdraw but give researchers the permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.		
3) I wish to withdraw fully, and for my samples and associated personal and clinical information collected to be destroyed and deleted		

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 need to provide a description of the circumstances below.*

--

### **Declaration by Study Doctor/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/ Researcher (please print) _____  Signature _____ Date _____
--

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