Participant Information Sheet/Consent Form
Person Responsible/Medical Treatment Decision Maker
Melbourne Health

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

Part 1: What does participation involve?

1. Introduction

The participant is invited to take part in this research project, Markers in Neuropsychiatric Disorders (MiND). This is because their doctor has identified that they have neurological, neurocognitive or neuropsychiatric symptoms.

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 the participant 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 the participant should take part, you might want to talk about it with a relative, friend or the participant's doctor.

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

If you decide you want the participant 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 for the participant to take part in the research project
• Consent the participant to have the tests and research that are described
• Consent to the use of the participant's 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 the participant provides, and all their 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?

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 for the participant 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. The participant's medical care will happen as normal. It will not be affected by participation in this study and there will be no consequences or negative impact on their normal course of treatment and care if they participate, or if you decide to withdraw them from the study at any time for any reason.

By agreeing for the participant to be involved in this research study, you are agreeing to:

1. **Sign the consent form**
2. Permission for the study to **collect a blood sample,** similar to a standard clinical blood test and should take less than 15 minutes, for testing of the biomarker neurofilament light
3. Permission for the study to **collect relevant information from the participant's standard, routine medical care,** from medical records and treating doctors, which will allow us to properly understand and interpret biomarker levels
4. 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 regular medical appointments. This may not always be possible, therefore, to reduce inconvenience, we will provide a range of options, for example: to complete consent, questionnaires and surveys over the telephone or online, and to provide a blood sample at a local community pathology service. If the participant is providing samples for tests as part of their standard clinical care, we will try to use remaining samples for this research study, in order to reduce any additional procedures for them.

If you agree for the participant to participate in the study you are also giving permission for the study to collect relevant information from their 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 the participant's routine clinical care could include information such as personal information (e.g. education, employment status, lifestyle factors), details about 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 agreeing to participation, you are providing access to the participant's 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:

- Give permission for the participant 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 the participant's local doctor be advised of your decision to participate in this research project. If they have a local doctor, we strongly recommend that you inform them of their participation in this research study.

4. Does the participant have to do anything differently? Can they have other treatments during this research project?

Participation in this study does *not* change anything else in the participant's healthcare and standard clinical treatment. There are no lifestyle or dietary restrictions, or other changes needed just because they are participating in this study. They should follow their usual clinical treatment with and advice from their treating doctors and other healthcare professionals, and continue to take their usual, regular medications. They 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 the participant's samples *may* be used for genetic research in the future
    - 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
    - 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

- 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. The participant's data will only be used for pooling data from lots of other participants and only for research purposes, will **not** identify the participant or their family personally in and scientific publications, will **not** be put in their medical records, and will **not** be shared with them or their family. Like all other data, this data will be stored securely. As the participant, their family, or their treating doctors will not receive any of this research genetic information, this means that any genetic research will **not** have any insurance or employment or hereditary implications for the participant or their family

6. Does the participant have to take part in this research project?

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

Your decision whether the participant should take part or not take part, or to take part and then withdraw, will not affect their routine treatment, their relationship with those treating them, or their relationship with the Royal Melbourne Hospital.

If you do decide for the participant 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 the participant will directly benefit by taking part in this research study, because the most important health benefits will be realised years from now. However, their 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. The participant may have none, some or all of the effects listed below. If the participant has any of these side effects, or are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

- **Blood collection**:
  - The blood test the participant will have in this study will follow the same procedure as a blood test the participant would have in their 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 the participant. It may also reveal something about the participant that is unrelated to their 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 the participant's treating doctor, to then discuss and return the findings to you and the participant:
    - 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 the participant 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 the participant suffers 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

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

Even after the participant's 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 for the participant to participate will not affect their medical treatment in any way. Your decision whether they take part or not, or to take part and then withdraw, will not affect their relationship with the researchers or their doctor, or Royal Melbourne Hospital. If you choose for them 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 the participant that have already been collected. You may also give the study permission to collect relevant follow-up information from the participant's medical records for use in research and analysis. However, you or the participant will not be personally contacted by the study from then on. Should you choose to fully withdraw consent, the study will discard the participant's stored samples and associated personal and clinical information. However, if some or all of 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 the participant 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 the participant's 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 participation, with you and the participant. 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 the participant?

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal and medical information about the participant for the research project. Information about the participant may be obtained from their 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 their participation in this research project, and critical for the study's success. Information about their participation in this research project may be recorded in their health records. Any information obtained in connection with this research project that can identify them 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 the participant 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 the participant's 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 the participant 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 the participant's test samples?

The blood samples collected from the participant 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, the participant's remaining samples will be stored indefinitely and used for any future unknown, unspecified medical research.

The participant's samples may be shared with study researchers in Australia and overseas in order to achieve the aims of this research study. If their samples are shared with study researchers outside of Melbourne, their 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 their 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 the participant and their privacy.

The participant's samples will be re-identifiable, so that data from samples (such as biomarker levels) can be linked with their 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 their sample (i.e. re-identify the participant) if necessary. Their privacy is paramount; only study staff will have access to the re-identifable 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 the participant or their 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 the participant has any medical problems which may be related to their 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 the participant is 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 the participant's involvement 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	03 9342 8530
Email	research@mh.org.au

Consent Form – Person Responsible/Medical Treatment Decision Maker

Title	Markers in Neuropsychiatric Disorders: investigating biomarkers and clinical markers in neuropsychiatric, neurological and neurodegenerative disorders
Short Title	MiND
Protocol Number	2020.142
Project Sponsor	The Royal Melbourne Hospital
Principal Investigators	Professor Dennis Velakoulis, Dr Dhamidhu Eratne and the Melbourne Health MiND Study Group
Location	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 the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.
I understand that I will be given a signed copy of this document to keep.
I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Melbourne Health concerning the participant's condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Optional parts of the research project (please initial under your preferred response)	**Yes**	**No**
I give consent to be contacted by researchers about future studies		

Declaration by Person Responsible/Medical Treatment Decision Maker

Name of Participant (please print) _____

Name of Person providing consent (please print) _____

Relationship of Person providing consent to Participant _____

Signature of Person providing consent _____ Date _____

Declaration – only for Person Responsible/Medical Treatment Decision maker unable to read the information and consent form
Witness to the informed consent process*
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible/medical treatment decision maker for 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 – *Person Responsible/Medical Treatment Decision Maker*

Title	Markers in Neuropsychiatric Disorders – investigating biomarkers and clinical markers in neuropsychiatric, neurological and neurodegenerative disorders
Short Title	MiND
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Principal Investigators	Professor Dennis Velakoulis, Dr Dhamidhu Eratne and the Melbourne Health MiND Study Group
Location	Melbourne Health

Declaration by Person Responsible/Medical treatment decision maker

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those treating them or relationship with Melbourne Health.

Options for withdrawing (please initial under your preferred response)	**Yes**	**No**
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) _____

Name of Person providing consent (please print) _____

Relationship of Person providing consent to Participant _____

Signature of Person providing consent _____ 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 person responsible/medical treatment decision maker for 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.