Participant Information Sheet and Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	MiNDAUS NH&MRC Partnership. Motor Neurone Disease: Patient centered care for a progressive neurological disease-evidence driving policy.
Short Title	MiNDAUS Clinical Registry
Protocol Number	RES-21-0000-058A
Project Sponsor	University of Sydney
Coordinating Principal Investigator **Site Principal Investigator**	Assoc Prof. Paul Talman *Site to complete*
Site Location	*Site to complete*

Part 1 What does my participation involve?

1. Introduction

a. Background

In an effort to improve care and the coordination of care for people with MND and their carers, leading MND Specialists and researchers partnered with organisations that provide support, care and advocacy. This group became the MiNDAUS (pronounced MindOZ) Partnership, which in 2018 received funding from both the National Health and Medical Research Council, from MND Charities as well as private donations.

The MiNDAUS Partnership has constructed a secure online platform which has two distinct parts: The MiNDAUS Patient Registry, and the MiNDAUS Clinical Registry.

b. Your Invitation

You are invited to take part in the MiNDAUS Patient and Clinical Registry because you have been diagnosed with Motor Neurone Disease (MND), also known as Amyotrophic Lateral Sclerosis (ALS). Your participation is important because collecting information from many people will allow expert Clinicians to better understand the different forms MND takes and what might cause the differences. Analysing the data collected will also help us to understand how safe and effective different treatments and medicines might be. Participating will also make it easier for you to take part in other research projects, such as clinical trials.

The MiNDAUS **Patient** Registry will allow you the choice of recording information about yourself and your specific needs on a platform which makes it easy to complete, easy to update and easy to share with people that you choose. Taking part in the Patient Registry is simply a matter of registering yourself and entering the information you think is important. You will be given the opportunity to link your information on the Patient Registry to the Clinical Registry which is completely up to you.

The rest of this form relates to the MiNDAUS **Clinical** Registry in particular.

c. About this form

This Participant Information Sheet/Consent Form tells you about this project. As long as we have your permission, we will collect information about you and your illness. 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.

d. About Consent

If you decide you will take part in project, you will need 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 MiNDAUS Clinical Registry.

• 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 project?

a. Significance

The MiNDAUS Clinical Registry will replace the Australian Motor Neurone Disease Registry (AMNDR) which has been collecting clinical information since 2004. This resource is critically important and will be included with the newly collected information for future analysis. If you are already enrolled in AMNDR, your AMNDR ID will link your old information to new data that is collected about your illness.

This registry will share clinical data that strengthens other research activity including scientific studies, clinical drug trials and health service delivery studies. Our aim is to ensure focused and best practice outcomes for patients with MND.

b. How will the MiNDAUS Clinical Registry contribute to care and research?

To improve coordination of care the MiNDAUS partnership group aims to combine the efforts of researchers, clinicians and support agencies to make collection of clinical data more focused and relevant to an individual's care needs. We will keep improving the system so that it easily connects participant's information between clinics and support agencies which will enhance care coordination.

An important priority for the MiNDAUS Partnership is to use the gathered data to develop National Polices and health care strategies that will help to ensure all people living an MND have fair access to research and participation in clinical trials. .

In particular, The MiNDAUS Clinical Registry will share and integrate your data with the Sporadic ALS Systems Genomics Consortium (SALSA-SCG) if you are enrolled in both studies.

c. How is MiNDAUS funded?

The MiNDAUS Patient and Clinical Registry has been partly funded by the Australian National Health and Medical Research Council (NHMRC) which has provided funding for this project for 5 years, under the 'Partnering with Consumers' Grant scheme. The funding for this type of grant relies on an equal amount of funding being obtained from the community. Our community funding has been obtained from the following sources:

- Motor Neurone Disease Research Association (the research arm of the Motor Neurone Disease Association of Australia)
- Australian Motor Neurone Disease Registry
- Motor Neurone Disease Association of Western Australia
- Thomas MND Research Group
- Motor Neurone Disease Association of Australia
- MND and Me Foundation

In addition, MiNDAUS benefits from work that was started from funding from other sources. In particular:

- Foundation for Angelman Syndrome Therapeutics
- Racing for MNDi Foundation
- FightMND
- The Ice Bucket Challenge
- MTP Connect

3. What does participation involve?

The information collected by the clinical registry is obtained from normal routine clinical visits, there are **no** interventions involved in participating in this project. The project team, including your Neurologist, will collect information about your MND diagnosis, general health history and family history, physical measurements (height and weight) and lifestyle such as smoking and your occupation. They will also administer the ALS Functional Rating Scale (ALSFRS) interview, which collects information about your physical abilities such as movement, dressing and eating.

4. What do I have to do?

You will not be required to attend any extra appointments for participating in the MiNDAUS Clinical Registry. We will collect this information during your routine clinic visit. If you cannot attend clinic, telehealth can be used to collect most of the information.

You can continue to take your usual medication and we will record your use of both prescribed and over the counter medications.

You are encouraged to follow the advice of your healthcare team and we will record your contacts with different health care professionals. This will help us to understand where access to services needs improvement.

You can continue to participate for as long as you want to. You may withdraw your consent at any time and at any point in the study. There are no costs associated with participating in this project, nor will you be paid.

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 your treating team.

5. Other relevant information

a. Data access

Researchers wanting access to the MiNDAUS Patient and Clinical Registry data will be required to have ethical approval for their research. The MiNDAUS Registries Governance Committee will control access to the collected data to other researchers. Any scientists who wish to use your data must also agree to protect your privacy and store data securely.

The information gathered on the MiNDAUS Clinical Registry will be extremely useful for scientists trying to discover and understand the different forms of MND, and the processes that underly it. The data will also help clinicians and researchers understand different responses to treatments and will inform policy makers what effective support services look like for patients and their carers.

6. What are the possible benefits of taking part?

Your participation will be of no direct benefit to you. Although you may gain some insights into your disease the main effect of your participation will be to benefit understanding that this study will bring in improving diagnosis, treatment and care of people with MND living in Australia.

Participants in this or any other related projects cannot claim ownership rights to any medical or scientific product that results from research. MiNDAUS or another company may benefit financially from the outcomes of research projects that have used your health information in approved research projects.
We hope that our work will help people with MND in the future if we increase our knowledge to improve care and coordination of health care services as well as making a positive contribution to MND research programs in Australia.

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

The main risk to your participation in the MiNDAUS Patient and Clinical Registries is unauthorised access to your data. In order to minimise this risk, we ensure that we have:

a. A data management plan

The MiNDAUS Partnership has paid particular attention to the security of the data that is collected through the MiNDAUS Patient and Clinical Registries. The Registry platform is very secure, and your name and identifying details are kept separate to all your other information. There has been a comprehensive data management policy developed to ensure your privacy and the confidentiality of your information, in accordance with the Australian Privacy Guidelines (Office of the Australian Information Commissioner 2014) and the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, Australian Research Council et al. 2007)(Updated Nov 2018).

b. Adequate support and training for project staff

The Principal Investigators at each site ensure that their project and clinical staff are trained appropriately, and everyone involved takes their responsibility to your privacy very seriously.

Any information that identifies you will only be shared with your permission.

8. Does this project limit any therapies or interventions I can access or undertake to manage my disease?

There is no requirement to limit anything (supplements or interventions) you wish to undertake to assist you in managing your disease, as this project is observational and will only record your choices. Other therapies or interventions could include over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. This project will ask you to inform the project team through the patient registry or your clinician about any changes to these during your participation in the research project.

9. What if I withdraw from this project?

If you decide to withdraw from this project, please notify a member of the project team and no further details will be collected about you for the registry.

If you do withdraw your consent, the project team will not collect additional clinical information from you, although information already collected will be retained.

10. Could this project be stopped unexpectedly?

The principal investigators feel that the risk of this project stopping unexpectedly is very low. The main risk for this to occur is lack of funding. This project has been initiated with primary funding from the NHMRC and others as specified in Section 2c) but fully expects to attract further funding to continue it's aims.

11. What happens when the project ends?

The MiNDAUS Clinical Registry is expected to continue indefinitely. The data collected and stored in the MiNDAUS Patient and Clinical Registries will be have long term value and will be retained indefinitely under the supervision of the MiNDAUS Registries Executive and Governance Committees.

Part 2: How is this project being conducted?

1. What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant staff collecting and using personal information about you for this project and sharing your data with other projects in the future that are approved by the MiNDAUS Registries Governance Committee, if you agree specifically to this.

The health information data we share with other projects will not able to identify you but will contain a code that we can cross link to your personal details, which are held in a completely separate place.

2. How do we keep your information secure and private?

The MiNDAUS Clinical and Patient Registries are created on a modern, highly secure framework. This framework offers state of the art security features incorporated in every aspect from the programming language used, the design of the software, the security of access, and the way it is stored.

To provide the highest level of privacy protection, all traffic to and from the platform is encrypted, and any identifying data is kept in a separate place to clinical or self-reported data. This means that if someone unauthorised accessed your health data they would not be able to identify you.

The MiNDAUS Patient and Clinical Registries will be hosted on Amazon Web Services (AWS) Australian based servers and will be protected by AWS advanced security measures in addition to the securities inherent in the software itself and the security policies adopted by the MiNDAUS Partnership.

AWS is a trusted provider of hosting services by the Australian Federal Government

Information about you may be obtained from your health records held at this and other health services for the purpose of this project. By signing the consent form you agree to the project team accessing health records if they are relevant to your participation in this project.

3. Publication of results

It is anticipated that the results of this project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

4. Can I access the data collected about me?

If you agree to participate in both the MiNDAUS Patient and Clinical Registries, you will be able to view all the information collected about you on the Clinical Registry.

You have the right to request that any information with which you disagree be corrected.

5. Complaints

If you have a complaint about the conduct of a member of the project team, please talk to the 'Site Principal Investigator' in the first instance. This is the Director of the Specialist Clinic which you attend. Their name can be found on the first page of this document here.

You can also contact the Coordinating Principal Investigator Associate Professor Paul Talman on Ph: 03 4215 0713.

6. Who has reviewed the Project?

The ethical aspects of this project have been reviewed by the HREC of Monash Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

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 and HREC Executive Officer details

Reviewing HREC name	Monash Health HREC
HREC Executive Officer	Deborah Dell, Manager, Human Research Ethics Committee
Telephone	(03) 9594 4611
Email	Research@monashhealth.org

Consent Form - Adult providing own consent

Title	MiNDAUS Clinical Registry
Protocol Number	RES-21-0000-058A
Project Sponsor	University of Sydney
Coordinating Principal Investigator	Assoc Prof Paul Talman
Principal Investigator	Professor Matthew Kiernan
Site Principal Investigator	*[Site PI]*
Site Location	*[Location where the research will be conducted]*

Consent Agreement

Please tick either Yes or No for each of the statements below

	Yes	No
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 participating in the Registries.	☐	☐
I have had an opportunity to ask questions and I am satisfied with the answers I have received.	☐	☐
I freely agree to participate in the MiNDAUS Clinical Registry as described and understand that I am free to withdraw at any time during the project without affecting my future health care.	☐	☐
I give permission for MiNDAUS Project Staff to access my health records to ensure that the Clinical Data is complete.	☐	☐
I agree to link the information I have entered into the MiNDAUS Patient Registry with the MiNDAUS Clinical Registry. I understand that I will be able to view the Clinical Information but will not be able to change it myself. I also understand that if I find an error, I can ask my treating Neurologist for it to be corrected.	☐	☐
I understand that once I have agreed to link both parts of the Registry members of my Healthcare Team will be able to see the information I have entered on the MiNDAUS Patient Registry.	☐	☐
I understand that when I have linked both parts of the Registry my Healthcare Team will see the information I enter, however, I cannot rely on it as a method of urgent or emergency contact.	☐	☐
I give permission to link my AMNDR ID to the MiNDAUS Clinical Registry (if applicable).	☐	☐

I give permission to link my clinical information to SALSA-SCG (if applicable).	☐	☐
I give permission for the MiNDAUS Partnership to store the information and data collected from me indefinitely in a safe and secure manner, as described in this Information Sheet.	☐	☐
I authorise the MINDAUS Partnership to share my data with ethically approved future research projects, in accordance with strict guidelines as set out in the MiNDAUS Data Management Policy.	☐	☐
I understand that the storing of data will allow contact to be made with me if a suitable clinical trial/ research study becomes available, but I understand I am under no obligation to take part.	☐	☐
I understand that this signed document will be stored on the MiNDAUS Patient and Clinical Registry, but I am able to request a paper copy.	☐	☐
I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Site name]* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.	☐	☐

Declaration by Participant – for participants who have read the information

Name (please print) _____

Signature _____ Date _____

Declaration - for participants unable to sign the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
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/Senior Project Team member†

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

Name (please print) _____

Signature _____ Date _____

† A senior member of the project team must provide the explanation of, and information concerning the project.

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

References

NHMRC, Australian Research Council and Universities Australia (2007). The National Statement on Ethical Conduct in Human Research 2007 (updated 2018). Australian Government Department of Health and Ageing. Canberra, National Health and Medical Research Council**:** 116.

Office of the Australian Information Commissioner. (2014, 22/7/2019). "Privacy Principles Guidelines (combined 2019)." Retrieved 17 January, 2021, from https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines.