Application for Access to the MiNDAUS Registries

This form is required if you wish to request access to the MiNDAUS Clinical and/or Patient Registries.

Part 1: Principal Investigator (PI) Information

PI Name and Title:

PI Qualifications:

PI Affiliation/ Company:

PI Email:

PI Mailing Address:

Street Address 1

Street Address 2

City

State/ Providence

Zip/ Postal Code

Country

Proposed Research Partners, if relevant:

Project Sponsor, if relevant:

Part 2: Project Information

Project Title:

Project description, 1000 words max. Include:

- Purpose
- Specific aims
- Background
- Methods/ analysis
- Source of funding
- Reason for registry access

Time frame for project completion:

Has this project been reviewed by an Institutional Review Board (IRB) or Human Research Ethics Committee (HREC)? Yes ☐ No ☐

IRB/ HREC name:

IRB/ HREC approval number:

[INSERT PROJECT DESCRIPTION HERE]

Part 3a: Request Information

Requesting raw data file in .csv format: Yes ☐ No ☐

Data search only, please describe. Include the following:

- Timeframes (e.g individuals born from 1990 onwards, Riluzole use, FVC >60% predicted)
- Inclusion or exclusion criteria (e.g. males only, ALS-FTD diagnosis)
- Outline of request (e.g.)

[INSERT REQUEST HERE]

Part 3b: Data Elements Requested

If you are requesting a raw data file in .csv format, please check the boxes to indicate the data elements you require. Indicate any parameters for the dataset below (e.g. individuals born after 1 January 1970):

Exclusion criteria:

Module 0. Demographics (request all in this module ☐)

Demographics			
Patient Personal Details			
Date of birth (birth year only given)	☐	Country of birth	☐
Sex	☐	Living status	☐

Patient Address			
State	☐	Postcode	☐
Medicare, Health Insurance and Support Details			
Are you currently an NDIS participant?	☐	Are you eligible for the NDIS (under 65)	☐
Do you have a DVA card?	☐	Have you been referred for aged care support services via My Aged Care (MAC)?	☐
Are you receiving a community home care package?	☐	What level package are you receiving?	☐

Note: identifiable/ potentially reidentifiable information cannot be provided

Module 1. Patient Information (request all in this module ☐)

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Patient Information	Visit Date
First | Subsequent Visit	Patient Information	MND Clinical Site
First | Subsequent Visit	Patient Information	Height (in cm)
First | Subsequent Visit	Patient Information	Weight (in kg)
First | Subsequent Visit	Patient Information	BMI
First | Subsequent Visit	Patient Information	Consultation Type
First | Subsequent Visit	Patient Information	Telehealth Consultation

Module 2. Diagnosis Details (request all in this module ☐)

Please select if you require data from First Visit ☐, Subsequent Visit ☐Completion Visits ☐

Clinical Visit	Module	Field
First | Subsequent Visit |Completion Visit	Diagnosis Details	Diagnosis
First | Subsequent Visit	Diagnosis Details	MND confirmed by
First | Subsequent Visit	Diagnosis Details	Please specify

First | Subsequent Visit	Diagnosis Details	More than one opinion given?
First | Subsequent Visit	Diagnosis Details	Tests to assist with diagnosis
First | Subsequent Visit	Diagnosis Details	Please specify

Module 3. Presenting details (request all in this module ☐)

Clinical Visit	Module	Field
First Visit	Presenting Details	Ethnicity
First Visit	Presenting Details	Date of symptom onset
First Visit	Presenting Details	Region where symptoms began
First Visit	Presenting Details	Please specify
First Visit	Presenting Details	Located
First Visit	Presenting Details	Type of MND / Diagnosis
First Visit	Presenting Details	Date MND Confirmed
First Visit	Presenting Details	Dominant Hand

Module 4. Medical History (request all in this module ☐)

Clinical Visit	Module	Field
First Visit	Medical History	Status of mother at time of clinic visit
First Visit	Medical History	Age at Death (if known)
First Visit	Medical History	Age of Mother at time of clinical visit (if known)
First Visit	Medical History	If Age of mother at time of clinical visit is unknown or N/A, check this box
First Visit	Medical History	Status of father at time of clinical visit
First Visit	Medical History	Age at Death (if known)
First Visit	Medical History	Age of Father at time of clinical visit (if known)

First Visit	Medical History	If Age of father at time of clinical visit is unknown or N/A, check this box
First Visit	Medical History	Mother dementia status (patient report)
First Visit	Medical History	Father dementia status (patient report)
First Visit	Medical History	Ever smoked?
First Visit	Medical History	Packs x Years
First Visit	Medical History	Current smoking status
First Visit	Medical History	Co-morbidity: Other psychiatric conditions (select all that apply)
First Visit	Medical History	Please Specify
First Visit	Medical History	Co-morbidity: Other medical conditions (select all that apply)
First Visit	Medical History	Please Specify
First Visit	Medical History	Please Specify
First Visit	Medical History	Highest educational attainment (select one)
First Visit	Medical History	Occupation

Module 5. Region(s) affected by MND/ALS

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Region(s) affected by MND ALS	Bulbar Region - UMN
First | Subsequent Visit	Region(s) affected by MND ALS	Bulbar Region LMN
First | Subsequent Visit	Region(s) affected by MND ALS	Cervical Region - UMN
First | Subsequent Visit	Region(s) affected by MND ALS	Left, Right or Both

First | Subsequent Visit	Region(s) affected by MND ALS	Cervical Region - LMN
First | Subsequent Visit	Region(s) affected by MND ALS	Left, Right or Both
First | Subsequent Visit	Region(s) affected by MND ALS	Lumbar Region - UMN
First | Subsequent Visit	Region(s) affected by MND ALS	Left, Right or Both
First | Subsequent Visit	Region(s) affected by MND ALS	Lumbar Region-LMN
First | Subsequent Visit	Region(s) affected by MND ALS	Left, Right or Both

Module 5. Reflexes

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Reflexes	Upper Limbs - Biceps: Left
First | Subsequent Visit	Reflexes	Upper Limbs - Biceps: Right
First | Subsequent Visit	Reflexes	Upper Limbs - Supinator: Left
First | Subsequent Visit	Reflexes	Upper Limbs - Supinator: Right
First | Subsequent Visit	Reflexes	Lower Limbs - Knee: Left
First | Subsequent Visit	Reflexes	Lower Limbs - Knee: Right
First | Subsequent Visit	Reflexes	Lower Limbs - Ankle: Left
First | Subsequent Visit	Reflexes	Lower Limbs - Ankle: Right

Module 6. ALSFRS-R

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	ALS-FRS Calculator	Speech
First | Subsequent Visit	ALS-FRS Calculator	Salivation
First | Subsequent Visit	ALS-FRS Calculator	Swallowing
First | Subsequent Visit	ALS-FRS Calculator	Handwriting
First | Subsequent Visit	ALS-FRS Calculator	Do you have Gastrostomy / PEG?
First | Subsequent Visit	ALS-FRS Calculator	Cutting Food and Handling Utensils
First | Subsequent Visit	ALS-FRS Calculator	Cutting Food and Handling Utensils
First | Subsequent Visit	ALS-FRS Calculator	Dressing and Hygeine
First | Subsequent Visit	ALS-FRS Calculator	Turning Bed and adjusting Bed clothes
First | Subsequent Visit	ALS-FRS Calculator	Walking
First | Subsequent Visit	ALS-FRS Calculator	Climbing Stairs
First | Subsequent Visit	ALS-FRS Calculator	Difficulty of Breathing
First | Subsequent Visit	ALS-FRS Calculator	Difficulty of breathing when lying flat
First | Subsequent Visit	ALS-FRS Calculator	Respiratory Insufficiency

Module 6. ALSFRS-R total score

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	ALSFRS Score	ALSFRS Score

Module 7. Cognition

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Cognition	Does it seem that cognition is affected?
First | Subsequent Visit	Cognition	Confirmation of dementia
First | Subsequent Visit	Cognition	Please state
First | Subsequent Visit	Cognition	ECAS (Edinburgh Cognitive and Behavioural ALS Screen) test administered?
First | Subsequent Visit	Cognition	ALS-Specific Score
First | Subsequent Visit	Cognition	ALS-nonspecific
First | Subsequent Visit	Cognition	Behavioural score
First | Subsequent Visit	Cognition	Psychosis score
First | Subsequent Visit	Cognition	Total score
First | Subsequent Visit	Cognition	Other cognitive test administered?
First | Subsequent Visit	Cognition	Score
First | Subsequent Visit	Cognition	Date administered
First | Subsequent Visit	Cognition	Other cognitive test administered?
First | Subsequent Visit	Cognition	Score
First | Subsequent Visit	Cognition	Date administered

Module 8. Treatment status

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Treatment status	Riluzole
First | Subsequent Visit	Treatment status	Riluzole Treatment commencement date
First | Subsequent Visit	Treatment status	Riluzole Treatment cessation Date

Module 9. Other treatment information

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Other Treatment information	Tracheostomy
First | Subsequent Visit	Other Treatment information	Date of Surgery
First | Subsequent Visit	Other Treatment information	Tracheostomy and ventilation
First | Subsequent Visit	Other Treatment information	Date commenced
First | Subsequent Visit	Other Treatment information	Non-invasive ventilation
First | Subsequent Visit	Other Treatment information	Date commenced

Module 10. Respiratory Function tests

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Respiratory Function Tests	Respiratory / Pulmonary Function Tests Done
First | Subsequent Visit	Respiratory Function Tests	Date performed
First | Subsequent Visit	Respiratory Function Tests	Respiratory / Pulmonary Function Tests Done, not available
First | Subsequent Visit	Respiratory Function Tests	Date
First | Subsequent Visit	Respiratory Function Tests	FVC Predicted (%)
First | Subsequent Visit	Respiratory Function Tests	FVC Litres (L)
First | Subsequent Visit	Respiratory Function Tests	SVC Predicted (%)
First | Subsequent Visit	Respiratory Function Tests	SVC Litres (L)
First | Subsequent Visit	Respiratory Function Tests	SNIP
First | Subsequent Visit	Respiratory Function Tests	MIP
First | Subsequent Visit	Respiratory Function Tests	MEP
First | Subsequent Visit	Respiratory Function Tests	Oxygen Saturation % (SpO2) on room air

Module 11. Sleep tests

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Sleep Tests	Sleep Study / Overnight Oximetry
First | Subsequent Visit	Sleep Tests	Date of Sleep Study
First | Subsequent Visit	Sleep Tests	Date of Overnight Oximetry

Module 12. Medications

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Medication (Can create multiple)	Medications
First | Subsequent Visit	Medication (Can create multiple)	Dose
First | Subsequent Visit	Medication (Can create multiple)	Dose (unit of measure)
First | Subsequent Visit	Medication (Can create multiple	Method of administration
First | Subsequent Visit	Medication (Can create multiple)	Frequency

Module 13. Clinical Trial Information

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Clinical Trial Information	Clinical trial participation
First | Subsequent Visit	Clinical Trial Details (Can Create Multiple)	Name of Clinical Trial

First | Subsequent Visit	Clinical Trial Details (Can Create Multiple)	Start date
First | Subsequent Visit	Clinical Trial Details (Can Create Multiple)	End date (if applicable)

Module 14. Other therapies or novel treatments.

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Other therapies or novel treatments	Other therapies or novel treatments?
First | Subsequent Visit	Other Therapy Details	Describe other therapy
First | Subsequent Visit	Other Therapy Details	Start date
First | Subsequent Visit	Other Therapy Details	End date (if applicable)

Module 15. Adaptive devices used at this time

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Adaptive Devices Used At This Time?	Adaptive Devices Used
First | Subsequent Visit	Adaptive Devices Used At This Time?	Please Specify

Module 16. Nutrition/Feeding Tube

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Nutrition/Feeding Tube	Has a Feeding Tube been inserted?
First | Subsequent Visit	Nutrition/Feeding Tube	Date of insertion

Module 17. Health Care Professionals and Services

Please select if you require data from First Visit ☐, Subsequent Visits ☐or both ☐

Clinical Visit	Module	Field
First | Subsequent Visit	Health Care Professionals and Services	Select Health Care Professionals and Services Currently Used
First | Subsequent Visit	Health Care Professionals and Services	Please Specify

Module 18. Inpatient Care

Please select if you require data from Subsequent Visits ☐

Clinical Visit	Module	Field
Subsequent visit	Inpatient Care(multiple)	Has there been an inpatient stay since last visit?
Subsequent visit		Date of admission
Subsequent visit		Date of discharge
Subsequent visit		Reason for admission

Module 19. Registry Completion

Please select if you require data from Completion Visits ☐

Clinical Visit	Module	Field
Completion	Registry Completion	Reason for Completion
Completion		Date of Exclusion
Completion		Date of death
Completion		Date of last contact
Completion		From whom was this data obtained?
Completion		If Other, Specify
Completion		Survivability

Completion	If the patient is deceased, please answer the following	Please confirm the diagnosis at the time of death
Completion		Mode of Death
Completion		If Other, Specify
Completion		And select one of:
Completion		Place of death
Completion		If Other, Specify
Completion		In the two weeks leading to death, what medications were given?
Completion		If Other, Specify
Completion		In the two weeks leading to death, were any of these interventions initiated?
Completion		Date Oxygen commenced (if known)
Completion		Date BiPAP commenced (if known)
Completion		Date feeding tube inserted (if known)
Completion		Date Tracheostomy performed (if known)
Completion	Completion sign off	Comments
Completion		MND Clinical Site
Completion		Has the patient accessed information regarding Voluntary Assisted Dying (VAD)?

Data requestor's responsibilities

1. You must take all reasonable steps to protect the registry participants' personal information against security breaches or loss of information and preserve the confidentiality of participants in any form of presentation or publication of data. It is requested that that data cells with fewer than five (5) participants be further aggregated or not published in line with the *Guidelines for the Use and Disclosure of Health Data for Statistical Purposes.*

2. Where MiNDAUS Patient and Clinical Registry data is referred to, it is inferred that this includes the data held in the historical Australian Motor Neurone Disease Registry, and where 'sites' are referred to, this includes the sites that collect data in the MiNDAUS Clinical Registry and sites that collected data in the Australian Motor Neurone Disease Registry.

3. Any site PI whose site has contributed data from >=50 patients will be acknowledged as a co-author in any publication.

4. You must acknowledge the Australian Motor Neurone Disease Registry and its successor the MiNDAUS Patient and Clinical Registry in all presentations and publications involving the use of the data by including the following text:

> *The authors gratefully acknowledge the Australian Motor Neurone Disease Registry and the MiNDAUS Patient and Clinical Registry team for the use of Registry data to conduct this research. In addition, we would like to thank the patients, principal caregivers, and clinicians for their involvement in the Australian Motor Neurone Disease Registry and the MiNDAUS Patient and Clinical Registry.*

5. All articles prepared for publication must be submitted to the MiNDAUS Registry governance Committee before publication for review by the MiNDAUS Registry Governance Committee. This review will focus on the protection of the privacy and confidentiality of Registry participants and permission for publication will not be unreasonably withheld.

6. You must be prepared to contribute your results to the MiNDAUS Registry Data Repository once this has been commissioned.

7. You must report all posters, presentations, abstracts, manuscripts and reports to the data curator, who will forward them to the MiNDAUS Governance Committee and provide pdf copies for the MiNDAUS Patient and Clinical Registry for the bibliography and publication repository

8. At the end of your project's estimated timeframe, you must destroy or delete all data files, or advise the data curator that you wish to extend the project.

Data request approval process:

Please submit this form with the signed confidentiality agreement to the data manager at mindaus@mndaustralia.org.au The data manager will review your application for approval and will forward your application to the MiNDAUS Leadership group. This process will take 4 to 8 weeks.

Application for Access to the MiNDAUS Registries

Application and confidentiality agreement:

The MiNDAUS Patient and Clinical Registry has a policy to protect patient and caregiver personal information from unauthorised distribution and to ensure that data will only be used, shared, or stored in line with the Australian Federal Privacy Act and National Statement on Ethical Conduct in Humans. This is to provide the highest level of confidentiality for the patients and caregivers in the MiNDAUS Patient and Clinical Registry. Potential patient identifiers such as postal/ zip codes will not be provided unless necessary for the project and approved by the MiNDAUS Registry Governance Committee. Your institution will also need to sign the application and confidentiality agreement. Data should never be shared or used for marketing purposes.

The data will be provided to you via a secure transfer with the agreement that you will use the MiNDAUS Registry data responsibly for the exact purpose you requested. You agree not to disclose or share any information without written permission of the MiNDAUS Registry Governance Committee. You must provide evidence of ethical approval prior to data release if required. Once you complete your data analysis, you must destroy all data files. The MiNDAUS Patient and Clinical Registry must be advised of any publications and receive acknowledgement for provision of the data.

Acknowledgements

The Institution agrees to the terms of this Confidentiality Agreement and Data Application to be effective as of the date of the Institution's signature by an authorised representative. Please direct any questions to mindaus@mndaustralia.org.au regarding this agreement or application process.

Institution:

Authorised Representative name/ title:

Signature:

Date:

The principal investigator has read and agreed to comply with the conditions in the *Application for Access to the MiNDAUS Patient and Clinical Registry* and *Confidentiality Agreement* but not as a formal party:

Name/ Title:

Signature:

Date: