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.*

1. 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.
2. You must be prepared to contribute your results to the MiNDAUS Registry Data Repository once this has been commissioned.
3. 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
4. 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 curator at [catherine.hansen@deakin.edu.au](mailto:catherine.hansen@deakin.edu.au). The data curator will review your application for approval and will forward your application to the MiNDAUS Registry Governance Committee. This process will take 4 to 8 weeks.

**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 [catherine.hansen@deakin.edu.au](mailto:catherine.hansen@deakin.edu.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: