FIGHT MND.
IT TAKES PEOPLE

2025 FightMND Phase II/III Clinical Trial Grants

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Introduction

FightMND Call for Proposals:

Phase II/III Clinical trial applications for novel, high-potential treatments for people living with MND/ALS

APPLICATIONS OPEN:
04 November 2024

LETTER OF INTENT DUE:
16 December 2024, at 17:00 AEDT

SUBMIT LETTER OF INTENT TO:
FightMND Grant Management System at https://fightmnd.fluxx.io/

INVITATION TO SUBMIT FULL APPLICATION:
20 December 2024

FULL APPLICATION DUE:
24 March 2025 at 17:00 AEDT

RECIPIENTS NOTIFIED:
August 2025

FightMND is pleased to announce a call for Phase II/III clinical trial applications for novel, high-potential treatments in Motor Neurone Disease/ Amyotrophic Lateral Sclerosis (MND/ALS) within the Australian Clinical Trials Consortium of hospitals.

The call for clinical study proposals is intended for academic-industry partnerships including but not limited to pharmaceutical, bio-therapeutic/ biotechnology companies, academic institutions and universities, hospitals, and MND researchers throughout the world.

Up to **AUD $1,800,000** in support from FightMND is available per grant.

Potential Phase II/III clinical trials should include therapeutic interventions that have:

I. A pharmacodynamic marker that can measure whether the targeted pathway of interest has been a ected;

II. A plan to collect samples for biomarker studies; and

III. Shown promising e cacy in at least two (2) MND disease models, one of which must be a representative model of human sporadic MND (if targeted to sporadic MND).

Industry partnership applications are strongly encouraged with shared funding proposals.

Note: It is NOT an Australian Regulatory requirement for drugs to have an IND submission prior to commencement of projects in Australia.

Since infrastructure support is provided by this grant, applicants should contact FightMND prior to their grant submission to collaborate on the budget portion.

Research Objectives

The following research objectives govern the parameters of the trials:

- This program is intended to enhance opportunities for translational research with the central emphasis on clinical studies/trials;
- Research conducted would provide high quality data that could lead to efficacy or Phase III clinical trials;
- Clinical study proposals must include trials of novel drugs or drug combinations, devices, or management practices for the treatment of MND;
- Each application must propose one Phase II or Phase III clinical treatment trial. In this context, Phase II trials may be proof of concept trials that will be carefully designed to establish the safety of drug candidates in the target MND population, and explore the relationship between the dose and desired activity. Applications for Phase II randomised placebo-controlled trials are welcomed.

Applications will be reviewed by FightMND-selected reviewers and the FightMND Grant Review Panel (GRP). The following will be considered in making funding decisions (see “Selection Criteria” below for further details):

- Scientific rationale and merit, novelty, and value of the project;
- Feasibility of the clinical trial;
- Significance of the clinical question and potential to change clinical management to progress to Phase III testing and beyond.

The successful applicant will retain control of the trial as well as intellectual property relating to the therapeutic agent being investigated.

Applicants may request the full AUD $1,800,000 in research support or may request a smaller amount depending on the appropriate needs of the proposed study or program. A maximum of 10% indirect costs is allowable and should be included in the AUD $1,800,000.

Industry partnership applications are strongly encouraged with shared funding proposals.

Trial logistic and infrastructure support can be provided through a FightMND approved Contract Research Organisation (CRO) and can be a combination of any or all of the following clinical research support services:

- Access to ten (10) clinical sites across Australia with access to between 50 – 350 MND patients at each site allowing for ease of enrolment;
- Project Management;
- Grants and Contracts Management;
- Biomarkers and bio-banking;
- Investigator brochure preparation or nalisation;
- Start-up activities: site selection and feasibility, preparation and submission of Institutional Review Board/Ethics applications, Investigator meetings, contract negotiation;
- Site Initiation, monitoring, site management and close-out activities;
- Investigator meeting organisation, participation and close-out activities;
- Third party vendor selection and management;
- Study budget negotiation (sites and vendors) as well as budget management;
- Data management expertise with internal and external vendor capabilities;
- Biostatistician who is a specialist in neuroscience projects;
- Medical Monitoring capabilities;
- Utilising neurologists for this service as required;
- Data Safety Management Board selection, preparation of associated documentation, maintenance and assistance in report preparation;
- Regulatory assistance in preparation of IND packages, attendance at pre-IND, End of Phase 2 meetings and pre-NDA meetings;
- Medical writing, including Clinical Study Report preparation;
- Preparation of Standard Operating Procedures; and
- Training of site and study personnel in Good Clinical Practice.

Selection Criteria

Reviewers will provide an overall impact/priority score to re ect their assessment of the likelihood for the project to exert a sustained and powerful in uence on MND research and the potential for clinical impact on disease biology. This evaluation will be assessed based on the following five core criteria:

Significance

- Does the proposed clinical study bring forward a new potential therapy for people with MND?
- Is there su cient preclinical data (pharmacology, toxicology and e cacy) to support initiation of the proposed trial?
- Can the proposed clinical trial be initiated expeditiously?
- Does the study have a pharmacodynamics marker that can measure whether the targeted pathway of interest has been affected by the drug?
- Is there a proposed plan to collect, store, and analyse samples for biomarker or other patient characterisation studies?
- Does the proposed trial protocol, if completed successfully, provide a sound platform for e cacy and Phase III trials?

Innovation

- Does the proposed clinical trial employ novel concepts, approaches, and/or methods?

Design

- Is the conceptual framework, design, methods, and proposed analyses adequately developed, well-integrated, and appropriate to the aims of the study?
- Have potential problems and alternative strategies been considered?
- Is/are the primary endpoint(s) meaningful?
- Primary endpoints of the study should be validated and well-accepted by regulatory agencies.
- Secondary endpoints that are innovate and novel are encouraged to be included in the study design, with appropriate justi cation and path towards being accepted by regulatory agencies.
- Is there an e ective plan on how the investigative team will engage with people living with MND about this research and study outcomes?

Environment/Collaborative Potential

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Does the proposed study take advantage of useful collaborative arrangements with other industry partners?

Investigator(s)/Sponsor(s)

- Is the Primary Investigator (PI) or Sponsor appropriately trained/qualified to carry out the study?
- If the application includes Early-Stage or New Investigators, do they have appropriate experience, training and support?

Each criteria is scored out of seven by peer reviewers, according to FightMND guidelines. Please refer to Appendix 2 for scoring descriptors for Clinical Trial Grants.

Additional Considerations

Open-Science Standards and Data and Information Transparency

Open-science standards are encouraged by FightMND where possible, and research proposals demonstrating open-science practise and information and knowledge-sharing will be considered favourably (for further detail, see https://www.unesco.org/en/open-science/about).

To avoid the potential for duplication and allow for improvements in trial design and protocols, FightMND expect transparency on data and information relating to clinical trials, including the publishing of negative results and reasons underlying such results.

FightMND Values

The alignment of research proposals with FightMND values are also considered during review. These are:

Community – driving collaboration in the community, including knowledge sharing.

Integrity – supporting research excellence and research with high-impact potential.

Urgency – research that is driven by and demonstrates urgency.

Boldness – supporting innovative research that takes considered and justi ed risks aimed at developing a better treatment and/or cure for MND.

Efficiency – supporting research in a disciplined manner, being cognisant of proposed budgets and financial and non-financial costs.

Application Limits

Applicants are limited to four (4) submissions as an Investigator, of which a maximum of two (2) can be as Primary Investigator, across all schemes (excluding Fellowships).

FightMND Equity versus Efficiency Policy

FightMND recognises the importance of fairness in ensuring adequate resourcing in under-resourced areas, and in developing resourcing capacity for future investment and trials. However, given the overall vision of FightMND – which is to ultimately cure MND – and the overarching policy of urgency with which we wish to achieve this goal, we also recognise that our resources must be prioritised to maximise e ciency.

Within our grant review process, we highlight the importance of equity when applicants formulate their research protocols, particularly in the context of clinical trials. Those projects that include multiple clinical centres will be looked upon favourably, particularly when such designs do not negatively impact e ciency of delivery.

Privacy, Conflict of Interest

Privacy and Confidentiality

All information contained in applications forwarded to FightMND will be regarded as con dential. Documents containing personal information will be handled and protected in accordance with the provisions of the *Privacy and Data Protection Act 2014* (Vic). Personal information will only be disclosed with the permission of the individual to whom it relates, or where the Act allows.

Applicants consent to the information supplied as part of their application being disclosed for the purposes of the evaluation and administration of the application and grant. Such disclosure includes but is not limited to independent reviewers/ assessors, the FightMND Grant Review Panel (GRP), the FightMND Board, and relevant employees of FightMND involved in the research grant process.

Applicants acknowledge that announcement of funded Clinical Trial Grant applications will involve a dissemination of information to the public about their general nature.

Conflict of Interest – Reviewers and GRP

FightMND requires its independent reviewers and grant review panel to act in an ethical manner, declare con icts of interest, and withdraw from considering applications where such con ict does or may exist.

Acknowledgement of Support

Successful applicants are required to acknowledge FightMND in any publications, public announcements, media, and scienti c meeting presentations or discussion forums pertaining to research conducted. FightMND materials, logos, and images can be supplied for this purpose, if required.

Submission Guidelines

Letter of Intent

Submission of Letter's of Intent

FightMND will only accept Letter's of Intent submitted via the Fluxx Grant Management System, which can be accessed at the following link https:// ghtmnd. uxx.io.

All administrative information and Letter's of Intent, as outlined below, are to be entered into the application forms in Fluxx. Resources are available to help you with this new submission procedure.

- How to register a new user account in Fluxx (manual)
- How to submit a Clinical Trial Grant Letter of Intent (Step 1) in Fluxx (written manual)
- How to submit a Clinical Trial Grant Letter of Intent (Step 1) in Fluxx (guided video)

If you experience any issues or have questions regarding the submission process, please contact the FightMND Cure team at researchgrants@fightmnd.org.au.

FightMND Phase II/III Clinical Trial grant applications are accepted by invitation only. Invited Full Applications will only be considered if applicants have submitted a Letter of Intent for review.

Requirements for Submitting a Letter of Intent

A Letter of Intent must include the following:

1) Application Form

Details on the Application form will be entered directly into FightMND's Grant Management System (Fluxx) at https://fightmnd.fluxx.io/, and will include the following:

- Primary Investigator information;
- Administering Institution information;
- Project title;
- Estimated project budget;
- Estimated duration of project;
- Estimated number of Australian patients to enrol, and Australian clinical sites;
- Proposed co-Investigator information;
- Lay summary of project (1500 characters)

2) Letter of Intent (3 pages max.)

Please use the template below as an example of the format required in submission of your letter of intent, to be uploaded with the application as a single pdf in FightMND's Grant Management System at https:// ghtmnd. uxx.io/.

Letters of intent should be prepared on A4 size pages with a minimum size 12 font (calibri preferred), one (1) cm minimum page margins and **must not exceed 3 pages** in length.

A brief CV of the Primary Investigator (2 pages max.) should also be added to the Letter of Intent pdf and uploaded onto FightMND's Grant Management System for consideration.

Letter of Intent - Template

Project Title:

Primary Investigator and Administering Institution:

Estimated direct costs for each year of funding:

Year 1 $
Year 2 $
Year 3 $

Estimated direct costs for the study: $
A maximum of 10% indirect costs may be included. The total budget including indirect costs cannot exceed AUD $1,800,000 (unless additional funding sources are available outside of this grant).

Estimated per patient cost for the study: $
Per patient costs should be appropriately budgeted to ensure equity of recruitment across clinical sites in Australia.

Primary Study aims:

Secondary Study aims (if any):

Briefl describe any relevant pre-clinical or clinical evidence that supports the study rationale.

Briefl describe the study design.

Indicate how the Primary Aims of this preliminary study will help optimise the design of the eventual definitiv phase III trial.

Describe how the intervention will be administered, including dose and duration as applicable.
Do you have the drug and placebo in hand for the trial?

Does this preliminary study include a placebo or control group/s? If "yes" provide applicable rationale. **YES** ☐ **NO** ☐

Does the trial drug have preclinical effica data in at least 2 MND models - one of which MUST be a representative model of sporadic disease? **YES** ☐ **NO** ☐

Describe the plan for sample collections and willingness to share samples with the MND research community.

Describe the pharmacodynamic markers that will be used in the trial.

Describe ethical and consent considerations of the proposed protocol.

Participating pharmaceutical or device manufacturing company (if any):

Do you hold, or have you applied for an IND/IDE for this protocol? (Please note: it is NOT a requirement for trials in Australia) **YES** ☐ **NO** ☐

List all core services that you are interested in utilising from a FightMND approved contract research organisation (CRO) – see "Research Objectives"(above) for details.

Submission Guidelines

Full Application

Should you be invited to submit a full application, FightMND will only accept applications submitted via the Fluxx Grant Management System, which can be accessed at the following link https://fightmnd.fluxx.io.

All administrative information and project proposals as outlined below are to be entered into the application forms in Fluxx. Resources are available to help you with this new submission procedure.

- How to submit a Clinical Trial Grant in Fluxx (written manual)
- How to submit a Clinical Trial Grant in Fluxx (guided video)

If you experience any issues or have questions regarding the submission process, please contact the FightMND Cure team at researchgrants@fightmnd.org.au

Requirements for Full Applications

Applications must include the following:

Application Form

Details on the application form will be entered directly in to the Fluxx Grant Management System, and will include the following details:

- Primary Investigator and co-Investigators.
- Name of the Institution where the project work will be undertaken.
- Other collaborators (not listed as Investigators).
- Administering institution information
- A lay summary of the project suitable for media release if the application is successful (300 characters).
- A lay summary of the project suitable for publication on the FightMND website if the application is successful (1500 characters).
- A Statement on the potential impact of the Clinical Trial (1250 characters).
- A summary of how you will engage with people living with MND about this research.
- A summary of how you will engage with people living with MND about this research (750 characters).

Project Proposals

Proposals must be uploaded as one pdf le onto Fluxx (max 5MB) and contain the following details:

Summary/Overview

(1 page max.)

- The summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application.
- State the project application's broad, long-term objectives and speci c aims making relevance to FightMND's mission of discovering e ective treatments and ultimately a cure for MND/ALS.
- Describe concisely the research design and methods for achieving the stated goals.
- This section should be informative to other persons working within MND/ALS research and/or clinical trials, and understandable to a scienti cally or technically literate non-expert.

Research Plan

(7 pages max.)

- Background data and signi cance.
- Preliminary Studies.
- Research design and methods (study design; participant description, data to be collected; plan of analysis).
- A summary of how you will engage with people living with MND about this research.
- A summary of how you will engage with people living with MND about this research.
- Appendix materials are allowed, including material to demonstrate that the treatment is ready for testing in humans. Please note, it is NOT a regulatory requirement for drugs to have an IND submission prior to human trials in Australia.

References
(2 pages max.)

Timeline
(1 page max.)

- Include a detailed timeline for the project milestones in Gantt chart format, that encompasses the delivery of research aims, milestones and outcomes, and demonstrates that the trial will be conducted expeditiously.
- An extension of the body of the 'Project Plan and Background' into the timeline page will make the application ineligible.
- The timeline should ALSO be uploaded as a separate file directly into Fluxx.

Budget and Justi cation
(2 pages max.)

- Applicants are strongly encouraged to contact FightMND in regard to budgeting and use of a FightMND approved Contract Research Organisation (CRO).
- Provide a full budget and budget justification. Note that continuity of funding is dependent on achieving study milestones (see below). Please consider this when planning the budget for your clinical trial application.
- Where the application is to support a Phase II/III Clinical Trial with a budget that exceeds the FightMND grant, applicants should include budget details of the entire study, including:
  - o The overall budget and cost of the study;
  - o The component of the study that this application will fund;
  - o Whether the TOTAL amount of funding required for the entire study has been secured, and the TOTAL funding amount so far secured for the study;
  - o If the TOTAL amount of funding required for the study has not been secured (other than the amount requested in this application), indicate the:
    - Approach that is being made by the applicants to secure the additional funding; and
    - Anticipated timeframe to secure the additional funding.
- Per patient costs must be included and clearly identi able in the budget section of the application. Per patient costs should be appropriately budgeted to ensure equity of recruitment across clinical sites in Australia.
- All budgeted items must be listed in $AUD.

Milestones
(0.5 page max.)

- Applications for a Phase II/III clinical trial must include clear Project/Study Milestones that align with the proposed budget.
  Milestones can include, but are not limited to:
  - o Human Research Ethics Committee (HREC) approval for the study;
  - o At enrolment of the first study participant;
  - o After enrolment of 25% of study participants;
  - o After enrolment of 50% of study participants;
  - o At completion of all study visits and database lock.
  - o Final report received by FightMND.

Note: Meeting milestones is an important requirement for Phase II/III clinical trials supported by FightMND Clinical Trial Grants. Continuity of funding is dependent on milestone achievement, and future payment instalments will not be made until the relevant milestone has been achieved. Please consider this when planning your study, milestones and budget.

Curriculum Vitae of all Investigators
(3 pages max. per Investigator)

Include:

- Academic background;
- Present and past employment positions;
- Awards and Prizes;
- Research grants support (past 5 years); and
- Peer reviewed publications (do not include publications "in preparation" or "under review"). Please provide a DOI number for papers recently accepted.

Declaration of Other Funding

Declaration and details of research funding from other sources (actual or proposed) that relate to this clinical trial application must be stated and include:

- Investigator, and Title of other Application;
- Funding Source/Organisation and Application ID;
- Role of Investigator on other Application;
- Duration of other funding; and
- Total amount requested.

The following components are to be uploaded in to the Fluxx application form separately to the project proposal:

Timeline

(max. 1 page).

- Upload a copy of the Gantt chart timeline as a separate file directly into Fluxx.

Budget

- Provide a high-level budget summary of total expenditure per year, entered directly into Fluxx (see page 10 of instruction manual, or instruction video at 4:13).

  Please see BUDGET AND JUSTIFICATION above for an overview of approved budget inclusions.

- Note that this should be the same expenditure as presented in the 1 page budget within the PDF proposal, but entered separately in Fluxx as high-level line items.

How to Submit

All applications are to be submitted through the FightMND Grant Management System Fluxx (https://fightmnd.fluxx.io).

- Select “Clinical Trial Grants” in the Fluxx Grant Management System to access the Clinical Trial Grant application form;
- The Project Proposal should be submitted as a single PDF (minimum size 12 font – calibri preferred, minimum 1 cm page margins), uploaded onto the Application form on the Fluxx Grant Management System (PDF size not to exceed 5MB).

The Project Proposal should include the following components:

- Summary/Overview;
- Research Plan;
- References;
- Timeline;
- Budget and Justi cation;
- Milestones;
- Curriculum Vitae of All Investigators;
- Declaration of Other Funding;
- Appendix Materials (see research plan – above).

- The TIMELINE should also be uploaded separately into the Application form on the Fluxx Grant Management System.

Applicants are limited to four (4) submissions as an Investigator, of which a maximum of two (2) can be as Primary Investigator, across all schemes (excluding Fellowships).

Application deadlines are described in this guideline.

Applications will NOT be accepted if submitted via email.

Reporting

Funding recipients will be required to submit reports on a regular basis via the Fluxx Grant Management System (details will be provided to successful applicants). The reporting schedule is outlined in the following table.

REPORT	REPORTING FREQUENCY	DUE
Progress against pre-determined milestones and/or targets *	6-monthly	Every 6 months from receipt of funds
Financial Reports (to be included in progress report) *	Annually	Every 12 months from the receipt of funds
Final Report	Once Only	At project completion, or within 12 weeks after project completion.
Milestone Noti cation for Phase II/III Clinical Trials	As agreed to in Grant Agreement	When Milestone is achieved
Ad hoc reports *	As requested by FightMND	On request with a negotiable time frame not greater than six weeks
FightMND Research Symposium Presentation	Biennially	During FightMND Research Symposium

* These reports will be used to assess whether the Clinical Trial is proceeding satisfactorily, whether funds are being acquitted in accordance with the original application goals, and to ascertain the ongoing value of FightMND funding.

Funding may be suspended if progress is considered unsatisfactory, or if funds have not been utilised in accordance with the Clinical Trial Grant Agreement.

Terms and Conditions

FightMND Grants

Terms and Conditions

All communication concerning Clinical Trial Grant applications and administration should be addressed to the FightMND Cure team at by email to researchgrants@ ghtmnd.org.au.

1. Proprietary Rights

1.1. The Primary Investigator/Administering/ Sponsoring Institution will maintain full control of scienti c work and all corresponding responsibilities. A scope of work will be agreed upon by all parties prior to initiation of funding. If necessary, con dentiality agreements will be incorporated.

2. Funding arrangements

2.1. FightMND Research Grants are time-limited, and applicants should ensure that proper consideration is given to this in the proposal. When the study is approved in principle, the initial sum awarded by FightMND will be for the rst Milestone only. Approval of funding for subsequent invoices will be subject to: availability of funds; the receipt from the grantee and/or Administering Institution of achievement of agreed milestones; and the receipt from the grantee and/or Administering Institution of satisfactory project progress and nancial reports. Members of FightMND team and Board will review milestone achievement, and progress and nancial reports to decide outcomes.

2.2. If the applicant under-spends in any year, FightMND can, at its discretion, give approval for the balance to be carried into the following year. Expenditure beyond the end date will only be permitted if authorised by FightMND in advance. Requests must be made by contacting FightMND at least eight weeks prior to the original completion date, by email to the FightMND Cure team at researchgrants@ ghtmnd.org.au.

2.3. The value of FightMND Phase II/III Clinical Trial Grant (or EAP where applicable) is up to a total of $1,800,000 AUD for performance of up to three (3) years.

2.4. FightMND will not meet indirect or overhead costs or on-costs of the Administering and/or Sponsoring Institution, such as: general travel, nance services, sta facilities, sta development, public relations, institutional libraries, routine secretarial work, personnel services, stationery or contributions to general departmental costs, and publication costs (except for those necessary to enable open access for publications).

2.5. Conference attendance: FightMND will allow up to $5,000 per annum towards the cost of relevant conference attendance and participation by the Primary Investigator and/or speci ed co-Investigators and research personnel relevant to the project, to be drawn from the total sum awarded. This may be used during the life of the project towards the costs of registration fees and travel, but not to cover separate hotel accommodation or other subsistence costs. Invoices, receipts or other evidence of spending must be provided. Investigators are encouraged to present their work, and the Primary Investigator is expected to attend at least one relevant meeting per year.

2.6. Payment of instalments is conditional on achievement of agreed milestones, and receipt and approval of satisfactory project progress and nancial reports (see condition 2.1 and 15.1).

2.7. Funding from other sources: nancial support for clearly de ned aspects of a project from separate funding sources is permitted under FightMND grants. Such supplementary funding must be disclosed at the time of the grant application or at the time such funding is received.

3. Ethical Considerations.

3.1. It is the responsibility of the applicants to have ethical committee approval for the planned research. This should ideally be in place at the time of funding being awarded.

3.2. Approvals must be received, and copies provided to FightMND upon request, prior to the research commencing.

4. Personal Direction of the Project

4.1. It is expected that the Primary Investigator will be actively engaged in directing the project. Continued use of FightMND funds during a prolonged absence of the Primary Investigator requires written agreement to continue the research under the direction of another quali ed Investigator, ideally obtained prior to the absence. The grantee or an approved representative of the Administering/ Sponsoring Institution must apply to and notify FightMND by email to the FightMND Cure team at researchgrants@ ghtmnd.org.au, with an explanation of the situation, providing details of the arrangements for conducting the research during their absence (see Terms and Conditions 11.2).

5. Recruitment and Employment of Sta

5.1. FightMND does not act as an employer and, therefore, in all cases where nancial support is provided for the employment of sta , the Administering or Sponsoring Institution undertakes to issue a contract of employment in accordance with any other relevant Act relating to the conditions of employment.

5.2. FightMND will not be responsible for claims under statute or at common law, nor will they indemnify the Administering or Sponsoring institution against a claim for compensation or against any claims for which the Institution may be liable as an employer or otherwise.

6. Sta Management Responsibility

The Administering/Sponsoring Institution must accept full responsibility for:

6.1. The management, monitoring and control for all sta (permanent, temporary and students) employed or involved in any research funded by a FightMND grant;

6.2. The management, monitoring and control of all research work funded as a result of a FightMND grant.

7. Termination of Employment

7.1. If the tenure of the appointment of sta recruited to work on the FightMND-supported project continues beyond the de ned period of the Grant, the Administering/Sponsoring Institution will be solely responsible for all costs beyond the period of the Grant. FightMND accepts no liability for contracts and costs extending beyond the de ned grant period.

8. Employment Term Contracts

8.1. Where members of sta have been under contract to the Administering/Sponsoring Institution prior to the activation of the FightMND Grant, FightMND will not reimburse costs attributed to any prior commitment. This includes any redundancy payments due for service prior to the grant period.

8.2. The contract of employment o ered must not extend beyond the termination of the Grant (unless the Administering/Sponsoring Institution wishes to extend the contract at its own expense).

9. Parental and Other Long-Term Leave

9.1. The Administering/Sponsoring institution will meet the cost of any long-term leave, other than holiday, and will ensure that all annual leave entitlement is taken within the Grant period. Long-term leave may include maternity, parental or long-term sick leave.

9.2. Parental leave is the responsibility of the Administering/Sponsoring Institution employing sta undertaking a FightMND project. Leave will be provided according to the Institution's local terms and conditions of employment. The costs of such leave are the responsibility of the Administering/ Sponsoring Institution and are not provided for by FightMND.

9.3. If a FightMND funded employee is due to take any planned long-term leave, the Grant Primary Investigator should inform FightMND of the dates in advance. This will enable discussion to decide whether the Grant should be suspended for the period of absence until full-time employment can be resumed (see Terms and Conditions 4 and 11.2). If unplanned long-term leave occurs, the Grant Primary Investigator or an approved representative of the Administering/Sponsoring Institution should contact FightMND by email to researchgrants@ ghtmnd.org.au as soon as possible to discuss the situation.

10. Activation of an Awarded FightMND Grant

10.1. FightMND Grants are activated on receipt of a signed Grant Agreement and receipt of the first invoice. If, for any reason, the start date of the project is delayed after the Grant Agreement has been returned, FightMND must be informed at once, a Grant Agreement Deed of Variation form completed, and a new start date agreed (see Terms and Conditions 11.2). If necessary, a revised Grant Agreement may need to be completed and returned.

10.2. If the Trial does not start within three (3) months of the original agreed start date, FightMND may withdraw the Grant offer. The grantee and/or Administering Institution will have to reapply for funding in a future grant round, in competition with other applicants at the time.

10.3. Ethical Approval: FightMND must receive evidence that ethical approval is in place prior to the Trial starting. Payment of invoices will be delayed until evidence has been provided. It is the responsibility of the Primary Investigator to have ethical approval for the proposed research and this should ideally be in place at the time of applying for funding.

11. Change of Terms of an Awarded FightMND Grant

11.1. Reallocation of funds from one expense heading of the approved budget to another, as detailed in the Grant Agreement, requires written permission from FightMND.

11.2. Grantees will be required to submit a letter to FightMND detailing any and all proposed changes to the Trial, and complete a Grant Agreement Deed of Variation. Letters/Deeds of Variation must be submitted (where possible) at least eight weeks prior to the changes taking place, and submitted for approval to FightMND by email to the FightMND Cure team at researchgrants@fightmnd.org.au. FightMND must be kept informed at all times of any changes to the original grant funded and the Grant Agreement.

11.3. Any request for major changes in the terms of the Grant, e.g. for additional staff or budget items, must be made in the form of a new and separate grant application, which will be considered in competition with all other new applications.

12. Changes to Conditions of an Awarded FightMND Grant

12.1. FightMND reserves the right to change the Terms and Conditions of FightMND Grants at any time. If this occurs during the lifetime of a Grant, the revised Terms and Conditions may be applied in place of those issued at the commencement of the Grant.

12.2. Successful applicants will be given at least 8 weeks' notice of any change to conditions of the Grant.

13. Early Termination of an Awarded FightMND Grant

13.1. FightMND reserves the right to terminate an awarded Grant at any time. Circumstances which might lead to termination include:

- Any breach in the Terms and Conditions under which the Grant was awarded;
- If the project has not started within three months of the agreed start date;
- The work is diverging markedly from the original approved Trial. The Grant Primary Investigator or an approved representative of the Administering/Sponsoring Institution must inform FightMND immediately when they are aware of a change of direction (see Terms and Conditions 11.2). There may, however, be circumstances in which the change is acceptable on scientific grounds;
- Failure to submit adequate progress reports, achieve milestones or serious and unresolvable problems identified by a site visit; and/or
- Work has ceased on the Trial/Grant, or the Primary Investigator has ceased to be actively involved in the project. FightMND must be informed immediately if this situation arises (see Terms and Conditions 11.2).

FightMND will endeavour to give 60 days prior notice before termination of an awarded Grant.

13.2. If a Grant is terminated, FightMND will meet costs properly and necessarily incurred under the Grant Agreement up to the termination date. However, payments will not, in aggregate, exceed the amount of the Grant remaining to be paid at the time of its termination.

13.3. In the event of work being discontinued by the Administering/Sponsoring Institution, written notification must be sent to FightMND, together with a report on the work carried out to date, setting out reasons for the termination.

14. Extension to an Awarded FightMND Grant

14.1. It is the responsibility of the Primary Investigator to apply for further support before the end of the Grant period, if this is required. Applications for an extension of support may be considered in isolation or as a new application in competition with other applications at the time of applying (see Terms and Conditions 11.2).

14.2. Adequate time (at least eight weeks), should be allowed for an application to be processed and FightMND accepts no responsibility for any costs incurred due to the failure of a grantee to make such an application in good time.

15. Reports

15.1. The Primary Investigator is required to submit the following reports:

- **Annual progress reports:** due every 12 months from the Grant start date, as stated on the executed Grant Agreement (see Terms and Conditions 2.1). A short summary in language intelligible to the lay reader should also be submitted for possible use in FightMND publications and on our website;
- **Interim reports:** brief six-monthly reports of no more than three pages on project progress;
- **Final report:** required within twelve weeks after completion of the Grant. A detailed final report covering the whole trial will be substituted for the annual report. In addition, a summary should also be provided in language intelligible to the lay reader. Researchers must avoid the use of jargon and technical language and should pitch the summary at the level of a science feature in a broadsheet newspaper. The summary may be used in FightMND publications;
- **FightMND Research Symposium:** the Primary Investigator is required to present progress of the project annually, and at the FightMND Research Symposium.
- **Noti cation of Milestone achievement:** FightMND should be noti ed and supporting documents provided when the Clinical Trial has achieved agreed milestones, by email to the FightMND Cure team at researchgrants@ ghtmnd.org.au.

15.2. Instalments of the Grant will be paid only after receipt of relevant and agreed milestone achievement and receipt of progress reports and their approval by FightMND. Payment may be delayed if reports are not submitted on time and/or if clari cation is required.

15.3. Feedback to people living with MND and/or Carers. All grantees are encouraged to provide regular information on their research to be circulated by FightMND for patients and carers. Where volunteers are involved in research, grantees are required to provide regular feedback to the participants and FightMND, in addition to annual reports and publications.

16. Site Visits and Progress Meetings

16.1. FightMND reserves the right to visit the grantee's research site during the period of the Grant to discuss project progress, and welcomes invitations to do so.

16.2. Grantees may be asked to attend six monthly progress meetings to discuss progress with FightMND representatives and donors. These may be arranged in conjunction with site visits.

16.3. Grantees may be asked to take part in FightMND communication projects such as video content to help facilitate feedback to FightMND's donors on outcomes related to the Grant.

17. Publications, Presentations, Acknowledgments and Publicity

17.1. Grantees are expected to seek publication of ndings in refereed journals during and as soon as possible during and after conclusion of the Grant (subject to Term and Condition 18). FightMND and the grantee and/or Administering Institution jointly undertake to notify each other before published reference is made to the ndings of the project, and to discuss and reach agreement on the form of publication wherever possible.

17.2. Grantees and/or the Administering Institution must inform FightMND immediately when results from FightMND-funded research are accepted for publication or presentation. The grantee and/or Administering Institution must provide FightMND with reprints, photocopies or electronic copies of the final version of any such publications.

17.3. **Open Access Policy:** Grantees are mandated to make their peer-reviewed papers, directly arising from the Grant, available through open access. These research papers should be available within the PubMed Central repository as soon as possible, but definitely within six months of publication. Costs to enable open access for publications can be included in the project budget.

17.4. **Posters – costs and accessibility:** If FightMND-funded research is accepted for presentation as a poster, the costs of poster production may be claimed as part of the consumables budget (to a maximum of $500 per Grant). The poster must acknowledge FightMND as a source of funding and should include FightMND's logo. FightMND should be provided with an electronic copy of the poster for use on our website and social media.

17.5. To ensure the long-term sustainability of income for research and to reflect and maintain our reputation for funding research of the highest scientific excellence and of greatest relevance to MND, all opportunities to promote FightMND must be pursued. The grantee and the Administering Institution are obliged to co-operate with FightMND over any publicity or fundraising activity arising from research funded by FightMND. Where it is the main funder of the research, FightMND reserves the right to lead on publicity.

17.6. Grantees and the Administering Institution must notify the FightMND Cure Research and Programs Director, Dr Bec Sheean, by email to bec.sheean@ghtmnd.org.au, the FightMND Cure team at researchgrants@ghtmnd.org.au, and the Marketing and Communications team at marketing@ghtmnd.org.au, at least five working days in advance of any publicity arising from research wholly or co-funded by a FightMND Grant. FightMND must be given at least 24 hours' notice of any media release in connection with the funded project. Any press release or other material including reference to FightMND-funded research must be approved by our team before it is released to the media.

17.7. In any oral or written report or poster presentation relating to FightMND-funded research, the grantee and/or author must acknowledge FightMND's support and display the FightMND logo where practical. All references to FightMND-funded work placed on websites, electronic bulletin boards and similar platforms must state clearly that the work is funded by "FightMND" and ideally a link should be included to FightMND's website: www.ghtmnd.org.au.

17.8. Grantees must ensure that FightMND's support is acknowledged in all publications, presentations and similar communications. It is essential for grantees to acknowledge that their research has been supported wholly or in part by FightMND, either in the text or in a footnote. The Grant reference/ID must also be provided.

17.9. When speaking publicly and to representatives of the media about FightMND-funded research, grantees and researchers should ensure they make it clear to the media and others that they should be presented as a "FightMND-funded scientist". Researchers should consult with FightMND's Cure Research and Programs Director, Dr Bec Sheean, at bec.sheean@ghtmnd.org.au and Marketing and Communications team at marketing@ghtmnd.org.au, before speaking to the media.

17.10. There is a subtle but important difference between speaking as a "FightMND-funded scientist" and acting as a spokesperson for FightMND. Representatives of the media may not always be aware of this difference. Grantees and Researchers who speak to the media must ensure that their personal views are not misrepresented as being attributable to FightMND.

18. Patents, Copyright and Other Intellectual Property

18.1. If ideas, processes or products of potential commercial value are generated as a result of the project, the Grantee and/or Administering/Sponsoring Institution must obtain the written consent of FightMND before taking any steps to exploit the results commercially. The Grantee and Administering/Sponsoring Institution accepts that FightMND may require a share of financial gain in return for its consent. This restriction shall continue to bind the parties notwithstanding any termination of the Grant. For further detail, please see Appendix 1 - Intellectual Property rights and commercial activities.

19. FightMND Meetings and Events

19.1. Grantees are asked to make themselves or other appropriate research team members available to report on the Grant project at FightMND meetings, fundraising events and occasionally at other times by invitation.

19.2. There may be occasions where the grantee or other appropriate research team members will be asked to present their work relating to the Grant project at scienti c and/or health care professionals' meetings.

19.3. When speaking and presenting at FightMND events, grantees or other appropriate research team members are expected to make it clear in the presentation their funding connection with FightMND.

20. FightMND Case Studies

20.1. Grantees are asked to make themselves available as case studies re ecting the work of FightMND for its wide-ranging communications and fundraising activities.

21. Scienti c Integrity

21.1. In the rare event of scienti c fraud occurring, FightMND wishes to make it clear that it is the responsibility of the employing authority to investigate any suspected case of fraudulent activity. FightMND agrees to provide funding providing the employing authority can produce evidence of a procedure for dealing with scienti c fraud. If fraud should be proven the Grant must be repaid in full to FightMND forthwith.

22. Indemnity

22.1 FightMND does not provide cover for negligent or non-negligent harm for participants in FightMND-funded studies. The Administering/Sponsoring Institution should ensure that local arrangements are in place should claims arise.

Appendix 1

Intellectual Property Rights and Commercial Activities

As a charity, FightMND is obliged to ensure that the outcomes of its funded research are applied for the public bene t. In some circumstances, this obligation may be best achieved through the protection of Intellectual Property resulting from the research and the facilitation of commercial exploitation of this Intellectual Property.

The term 'Intellectual Property' (IP) describes any work or invention that results from original creative thought.

IP falls into di erent categories:

- Copyright: protects written, dramatic and artistic work, software, lms, sound recordings and broadcasts.
- Patents: protects technical inventions, novel products or processes.
- Trademarks: distinguish the goods and services of one organisation from another.
- Design rights: protects the visual appearance of products.

Some of these protections need to be registered (trademarks, patents) and some do not (copyright, design rights). If the IP is not protected, another individual or organisation may copy the design or commercialise and sell the invention without consent or payment.

Therefore, for grants where FightMND funding may lead to the generation of intellectual property, the following additional conditions shall apply:

1.1. Any intellectual property developed during the course of conducting research supported by FightMND Grants under this agreement (Project IP) shall be owned by the Administering Institution.

1.2. The Administering Institution must comply with the National Principles of Intellectual Property Management for Publicly Funded Research by having in place strategies, policies, and procedures for the identi cation, protection, management, and exploitation of Intellectual Property, including that resulting from funding by charities such as FightMND.

http://www.arc.gov.au/national-principles-intellectual-property-management-publicly-funded-research

1.3. The Administering Institution should ensure that all persons in receipt of funding from FightMND, or working on funded activity (including employees, students, visiting sta and sub-contractors), are employed or retained on terms that vest in the institution all Intellectual Property arising from funding by FightMND.

1.4. The Administering Institution, grant holders and co-Investigators should inform FightMND of any pre-existing arrangements of which they are aware, and which could lead to a breach of FightMND-funded standard conditions. The Institution should take reasonable endeavours to ensure that no consultancies, third party restrictions or arrangements which might impact on a FightMND-funded grant are entered into in relation to any FightMND-funded person or activity without prior agreement of FightMND. FightMND-funded investigators or individuals involved in a FightMND-funded project should not use materials or compounds (other than those obtained commercially), on terms which would place restrictions on the publication of the results. Institutions should take reasonable endeavours to ensure that "reach-through claims" have not been granted on any FightMND-funded IP in favour of commercial organisations providing materials or compounds to FightMND-funded individuals for research purposes. However, FightMND recognises that companies providing materials may often require exclusive rights to any Intellectual Property arising from use of that material, and that this requirement is often non-negotiable. Where Intellectual Property arises from research linked indirectly to the use of material provided under such agreement, the provider should be o ered a time-limited opportunity to take out a revenue generating licence.

1.5. The Administering Institution and the Grant holders are bound to notify FightMND promptly in writing when new Project IP arises from the Grant and take reasonable steps to ensure that such IP is protected and not published or otherwise disclosed publicly prior to protection (whilst at the same time ensuring that potential delays in publication are minimised).

1.6. The Administering Institution should seek FightMND's consent to commercially exploit the results of any research it has funded. Consent will not be unreasonably withheld, and FightMND will only refuse an Administering Institution's request where it considers that the proposed commercial exploitation would run counter to its interests and charitable objectives. In the event that FightMND does not provide a response to the Administering Institution's request within thirty (30) business days, the institution or its technology transfer subsidiary will automatically have the right to proceed with such commercial exploitation. The Administering Institution is not required to seek FightMND's consent in assigning intellectual property to its technology transfer company.

1.7. Within thirty (30) business days of receiving the noti cation from the Administering Institution, and prior to the Administering Institution applying for registration of any Project IP, FightMND will advise the Administering Institution in writing which one of the following nancial arrangements will apply in relation to commercialisation of the Project IP:

I. All of the costs associated with commercialising of the Project IP (including patent and legal costs) will be paid by the Administering Institution. Out of any net proceeds received by the Administering Institution from commercialising the Project IP (after all of the Administering Institution's costs associated with commercialising the Project IP have rst been deducted), the Administering Institution will pay 10% of all net commercialisation proceeds to FightMND until such time as FightMND has received an amount equal to the amount of the Grant funding provided under this agreement multiplied by ve (5).

II. Ten per cent (10%) of the costs associated with commercialising the Project IP (including patent and legal costs) will be paid by FightMND as and when the costs fall due, and the remaining 90% of the commercialisation costs will be paid by the Administering Institution. Out of any net proceeds received by the Administering Institution from commercialising the Project IP (after all the Administering Institution's costs associated with commercialising the Project IP have rst been deducted and FightMND's costs have been reimbursed), the Administering Institution will pay 10% of all net commercialisation proceeds to FightMND in perpetuity.

III. FightMND will not seek any payment from the net commercialisation proceeds arising from commercialisation of the Project IP.

1.8. If the Administering Institution does not wish to protect, manage or exploit the IP, or fails to comply with the agreed strategy, FightMND may direct the Administering Institution to take steps to protect the IP at the Administering Institution's expense or to transfer the IP to FightMND.

1.9. If the Administering Institution wishes to use any third party (other than its recognised technology transfer company) to carry out its obligations with respect to IP, it must notify and provide details to FightMND.

Appendix 2

Scoring Descriptors for Clinical Trial Grants

The following descriptors are designed to provide peer-reviewers with benchmarks to aid in appropriately assessing and scoring individual grant applications. The descriptors are indicative rather than exhaustive.

EXCEPTIONAL SCORE – 7

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are *extremely well* defin d, *extremely* coherent and strongly developed, and justi ed *exceptionally*.
- has a *flawless* study design, methods, and proposed statistical analyses.
- meets and addresses all key criteria *exceptionally*.
- is *exceptionally* innovative and introduces *exceptional* advances in concept(s).
- is without question, *highly feasible* given that the team has all of the required expertise and research tools, resources, and techniques.
- has a sound scienti c basis with *exceptionally* robust preliminary data and *exceptionally* justifi d rationale.
- clearly outlines potential problems, limitations, risks and pitfalls, and identi es alternative approaches in an *exceptional* manner.
- has an *exceptional* research environment, demonstrable by existing infrastructure, mentoring and collaboration, and has an *extremely appropriate* balance of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry that *specifically targets* all aspects of the proposed research.

IMPACT AND FEASIBILITY

The planned research:

- involves several senior members with *exceptionally strong* national and international reputations in the MND/ALS research eld relevant to the study.
- (may) involve(s) junior members whose contributions to the overall team and research program are *extremely well-defined* and provide strong expertise targeted towards speci c aims of the study.
- will result in *exceptionally significant* advances in knowledge in the MND research eld and MND therapeutic development.
- if successful, will generate data *extremely likely* to provide a sound platform for e cacy and Phase III trials, and result in fast-tracking of the compound towards regulatory approval.
- will lead to *exceptionally significant* research outputs, including *exceptionally* in uential publications in world-leading peer-reviewed journals.
- will *without question* be the subject of invited presentations at *leading* national and international scienti c/clinical and MND/ALS meetings.
- has an *exceptionally well*-de ned next stage of clinical development with a realistic and achievable schedule and milestones.
- has an *exceptionally strong and extremely well*-de ned plan to engage with people living with MND about the proposed research and outcomes.

OUTSTANDING SCORE – 6

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are de ned in an *outstanding* manner, are *very highly* coherent and strongly developed, and justi ed *very well*.
- has an *outstanding* study design, methods, and proposed statistical analyses. with only a *few negligible* weaknesses.
- meets and addresses all key criteria in an *outstanding* manner.
- is *very highly* innovative and introduces *outstanding* advances in concept(s).
- is *highly feasible* given that the team has all of the required expertise and research tools, resources, and techniques.
- has a sound scienti c basis with *very highly* coherent and robust preliminary data and rationale that is justi ed *very well*.
- clearly outlines potential problems, limitations, risks and pitfalls, and identi es alternative approaches *very well*, with only a *few trivial* weaknesses.
- has an *outstanding* research environment, demonstrable by existing infrastructure, mentoring and collaboration, and a *highly appropriate* balance of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry that is targeted towards *all aspects* of the proposed research.

IMPACT AND FEASIBILITY

The planned research:

- involves several senior members with *outstanding* national and international reputations in the MND/ALS research eld relevant to the study.
- (may) involve(s) junior members whose contributions to the overall team and research program are *very well-defined* and provide *appropriate* expertise targeted towards the study's aims.
- will result in *very highly substantial* advances in knowledge in the MND research eld and MND therapeutic development.
- if successful, will generate data *very highly likely* to provide a sound platform for e cacy and Phase III trials, and result in fast-tracking of the compound towards regulatory approval.
- will lead to *very highly significant* research outputs, including *highly influential* publications in leading peer-reviewed journals.
- will *very likely* be the subject of invited presentations at *leading* national and international scienti c/clinical and MND/ALS meetings.
- has a *very well-defined* next stage of clinical development with a realistic and achievable schedule and milestones, with only a *small number of minor* concerns.
- has an *outstanding and very well*-de ned plan to engage with people living with MND about the proposed research and outcomes.

EXCELLENT SCORE – 5

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are de ned in an *excellent* manner, are *highly* coherent and strongly developed, and justi ed *well*.
- has an *excellent* study design, methods, and proposed statistical analyses, with *several minor* weaknesses.
- meets and addresses all key criteria in an *excellent* manner.
- is *highly* innovative and introduces *substantial* advances in concept(s).
- is *feasible* given that the team has the required expertise and research tools, resources, and techniques, with a *few minor* concerns.
- has a scienti c basis built on *highly* coherent and strong preliminary data that is justi ed *well*.
- outlines some potential problems, limitations, risks and pitfalls, and identi es alternative approaches with a *few minor* concerns.
- has an *excellent* research environment demonstrated by existing infrastructure, mentoring and collaboration, and a *highly appropriate* balance of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry that is targeted towards *relevant aspects* of the proposed research.

IMPACT AND FEASIBILITY

The planned research:

- has at least one senior member with an *excellent* national and international reputation in the MND/ALS research eld relevant to the study.
- (may) involve(s) junior members whose contributions to the overall team and research program are *well-defined* and provide *some* expertise targeted towards the study's aims.
- will result in *highly substantial* advances in knowledge in the MND research eld and MND therapeutic development.
- if successful, will generate data *highly likely* to provide a platform for e cacy and Phase III trials, and result in fast-tracking of the compound towards regulatory approval.
- will likely lead to *highly significant* research outputs, including *influential* publications in specialised peer-reviewed journals.
- will *likely* be the subject of invited presentations at *leading* national and international scienti c/clinical and MND/ALS meetings.
- has a *well-defined* next stage of clinical development with a realistic and achievable schedule and milestones, with *several minor* concerns.
- has an *excellent and well*-de ned plan to engage with people living with MND about the proposed research and outcomes.

VERY GOOD SCORE – 4

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are de ned *very clearly*, are coherent, logical and somewhat strongly developed and justi ed.
- has a *well-developed* study design, methods and statistical analyses – with a few concerns that overall should not impact on achievability.
- meets and addresses *most* key criteria *very well*.
- is innovative in its approach and introduces *some* advances in concept(s).
- is *feasible* given that most of the required expertise and research tools, resources, and techniques are present, with *several minor* concerns.
- has a scienti c basis built on coherent and *very good* preliminary data that is justi ed.
- outlines *some* potential problems, limitations, risks and pitfalls, and identi ed alternative approaches have *several minor* concerns.
- has a *very good* research environment inclusive of existing infrastructure, mentoring and collaboration, and an *appropriate* balance of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry that is targeted towards *some relevant aspects* of the proposed research.

IMPACT AND FEASIBILITY

The planned research:

- consists of all team members having *very good* and *growing* national and international reputations in the MND/ALS research eld relevant to the application, with a few minor concerns regarding the depth and breadth of expertise relevant to the study.
- (may) involve(s) junior members whose contributions to the team are *defined*.
- will likely result in *significant* advances knowledge in the MND research eld and MND therapeutic development.
- if successful, will generate data *likely* to provide a platform f or e cacy and Phase III trials.
- will likely lead to *significant* research outputs, including *strong* publications in specialised peer-reviewed journals.
- *may be* the subject of invited presentations at national and international MND/ALS meetings.
- has a *defined* next stage of clinical development with a realistic and achievable schedule and milestones, but there are *several* concerns.
- has a *very good*, de ned plan to engage with people living with MND about the proposed research and outcomes.

GOOD SCORE – 3

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are logical and *generally clearly* defin d, developed and justi ed.
- has a *generally clear* study design, methods and analyses – with several concerns that *may* impact on achieving study aims and results.
- meets and addresses *some* key criteria *well*.
- is solid in its approach, but is *minimally* innovative, and *may* introduce some advances in concept(s).
- is *generally feasible* given that some of the required expertise and research tools, resources, and techniques are present, with a *few concerns* that *may impact* on delivery of project aims.
- has a scienti c basis built on *good* preliminary data that is *somewhat* justifi d.
- outlines *some* potential problems, limitations, risks and pitfalls, and identi ed alternative approaches have *some major* concerns.
- has a *good* research environment, inclusive of existing infrastructure, mentoring and collaboration, with *some minor* concerns.
- has *good* evidence of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry, with *some minor concerns* on balance and relevance towards proposed research.

IMPACT AND FEASIBILITY

The planned research:

- team members have track records in elds relevant to the proposed research but with some *potentially significant concerns* regarding the depth and breadth of expertise relevant to the study.
- is comprised of a team with *established and growing* national reputations that does not yet have strong international pro les.
- addresses an issue of *some* importance or interest to, and may *moderately* advance capacity in, the MND research eld and MND therapeutic development.
- even if successful, is *unlikely to but may* generate data to provide a platform for e cacy and Phase III trials.
- *may* result in some *moderately significant* research outputs, including good but not excellent publications in specialised peer-reviewed journals that may have *moderate* in uence on the MND research eld.
- *is unlikely to be* the subject of invited presentations at national and international MND/ALS meetings.
- has *minimally discussed* the next stage of clinical development, and it *lacks clarity*.
- has a *good* plan to engage with people living with MND about the proposed research and outcomes.

MARGINAL SCORE – 2

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has objectives that are presented in a *satisfactory* manner, but *may lack clarity* in some aspects.
- contains *some major weaknesses* and raises *several significant concerns* with respect to the study design, methods or analyses which *are likely to* impact on the delivery of the project.
- is *somewhat feasible*, although there are *several concerns* around the required expertise, research tools, resources and techniques that are *likely to impact* on delivery of the project.
- *fails* to meet and address a number of key criteria.
- may have *some minimally* innovative and novel aspects.
- provides *minimal* preliminary data that is not clearly justi ed.
- has a *satisfactory* research environment inclusive of existing infrastructure, mentoring and collaboration, but there are *notable concerns*.
- has *some* evidence of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry, but relevance to the proposed research is *unclear*.

IMPACT AND FEASIBILITY

The planned research:

- includes team members that have *made contributions* to the research elds relevant to the proposal, but there are *several significant concerns* regarding the depth and breadth of expertise relevant to the study.
- is comprised of a team with national reputations that are *beginning to emerge* and only *limited* international pro les.
- addresses an issue of *marginal* importance or interest to, and *is unlikely to* advance capacity in, the MND research eld and MND therapeutic development.
- even if successful, *is unlikely to* generate data to provide a platform for e cacy and Phase III trials.
- is *unlikely to* result in signi cant research outputs or publications that in uence the MND research eld.
- *does not* have a de ned next stage of clinical development or it is *not* discussed.
- has *somewhat* de ned a plan on how the team will engage with people living with MND about the proposed research and outcomes, but is *lacking in clarity*.

UNSATISFACTORY SCORE – 1

RESEARCH PROJECT ASSESSMENT DESCRIPTORS

SCIENTIFIC RATIONALE AND TRIAL DESIGN

The proposal:

- has *unclear* objectives and scienti c approach.
- contains *several major* study design aws.
- raises *several major concerns* about feasibility and thus the likelihood of successful completion.
- *fails to* align with the key criteria.
- *lacks* innovation and novelty.
- provides *minimal and weak* preliminary data.
- has a *limited* research environment, *without access to* the necessary infrastructure, mentoring and collaboration.
- does *not* have evidence of cross-disciplinary approaches with researchers, clinicians, consumers, and/or industry.

IMPACT AND FEASIBILITY

The planned research:

- includes a team *deficient* in some areas of expertise required to successfully complete the study.
- is comprised of a team whose members are *not well known* nationally or internationally in the MND research eld, or relevant research eld, and *little or no evidence* is provided to demonstrate emerging track records.
- *does not* address an issue of importance or interest for MND research or MND therapeutic development.
- *will not* advance current knowledge and capacity in the MND research eld and/or MND therapeutics.
- *will not* generate data that will contribute to a platform for e cacy and Phase III trials.
- *will not* result in signi cant research outputs or publications that in uence the MND research eld.
- *does not* have a de ned next stage of clinical development.
- *does not* have a plan to engage with people living with MND about the proposed research and outcomes.