2021

RESEARCH GRANTS

FIGHT MND.

IT TAKES PEOPLE

DRUG DEVELOPMENT

RESEARCH GRANTS

CONTENTS

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ACRONYMS & DEFINITIONS

Administering Institution: Organisation that will be responsible for administration of the research project, and the receipt and distribution of grant funds. There can be only one Administering Organisation per grant.

Applicant: Researcher leading the research – the Primary Investigator (PI), who is responsible for the overall direction of the project, leading and supporting co-Investigators (CIs), completion and lodgement of the application, and progress and reporting on the project. The Applicant must obtain written commitment from their laboratory Head and Heads of Departments/Administering Institution, and must assume responsibility for undertaking and completing the activities outlined in the application. Where the project involves multi-site research, the Applicant must obtain written commitment from all Heads of Departments/Administering Institution of collaborative partners and co-Investigators not within the Administering Organisation.

Co-Investigator(s): Responsible for carrying out some aspects of the research under the guidance and leadership of the Applicant/Primary Investigator.

Collaboration and Collaborator/Collaborative Partner(s): All people, investigators and organisations involved in the Drug Development Project are considered to be collaborators. Collaboration may be between a combination of disciplines, departments and/or organisations. It includes organisations or individuals that provide specific resources that contribute to the research. Co-Investigators represent a specific sub-group of collaborators who are directly involved in the conduct of the project but are not responsible for the direction and progress of the project. By encouraging collaborative agreements, FightMND is asking researchers to consider looking beyond their discrete departments and organisations, and to seek out people who may be doing similar research. This may allow for stronger and higher quality research proposals and reduce research duplication.

Goods and Services Tax: Goods and Services Tax (GST) imposed in accordance with the *A New Tax System (Goods and Services Tax) Act 1999*, and related Acts and Regulations. GST will be paid on top of grant amounts where appropriate. This will be determined by the Administering Institution's GST status.

Motor Neurone Disease (MND): For the purposes of these Drug Development Grants, the definition of MND includes the following progressive neurological disorders that destroy motor neurons: Amyotrophic Lateral Sclerosis (ALS); Primary Lateral Sclerosis (PLS); Progressive Muscular Atrophy (PMA); Progressive Bulbar Palsy; and Pseudobulbar Palsy.

Translational Research: Research facilitating the transfer or translation of new basic knowledge of disease mechanisms gained in the laboratory into the development of new methods for the treatment and/or prevention of MND in humans.

Within this scope, research projects may include:

- the preclinical development of new treatments and interventions for MND; or
- testing the effectiveness of treatments for MND.

INTRODUCTION

FightMND Call for Proposals: Grant applications in support of preclinical research, development and assessment of therapeutics for MND/ALS through to (and including) completion of Phase I clinical trials.

Applications Open: 30 October 2020

Letter of Intent due: 15 January 2021, at 17:00 AEDT

Submit Letter of Intent to: researchgrants@fightmnd.org.au

Invitation to submit full application: 1 February 2021

Full application due: 1 April 2021 at 17:00 AEDT

Recipients Notified: August 2021

FightMND is pleased to announce a call for Drug Development Grant applications to support preclinical translational research through to and including Phase I clinical trials.

Grant applications will be considered for:

- **New Therapeutic Development Grants:** Supporting post-discovery, preclinical development of therapeutics for MND through support of a wide range of development activities ranging from validation of therapeutic leads to the submission of investigational new drug applications to regulatory bodies.

Applications supported by these grants must begin with identified lead compounds in hand.

- **Repurposing:** Supporting hypothesis-driven drug repurposing efforts focused on new therapeutics for MND.

Drug Development Grants are each awarded with an offer of up to **AUD $1,000,000** in support available for 3-year projects (Projects with a period of performance of less than 3-years will also be considered). Support will not normally exceed 3 years and applicants should submit proposals that are focused and compatible with a 3-year time period.

The continuation of a Drug Development Grant within this period will be subject to periodic review after the submission of satisfactory progress reports, which are required at six-monthly intervals. 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.

GRANT OUTLINE

The scope for these Drug Development Grants is as outlined below:

- Grants support the preclinical research, development, and assessment of therapeutics for MND through to (and including) completion of Phase I clinical trials. The proposed projects are expected to be product-driven and focused clearly on therapeutics, and it is anticipated that the agents and/or data generated from these projects will lead directly to the advancement of new therapies for MND to roll out into human clinical trials.
- There is a preference for drug development projects aimed at **sporadic** MND with the use of appropriate models of disease to justify such application.
- **Standards for Preclinical Study Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximise the reproducibility and translational potential of the preclinical research. An example of such standards is described in **Landis, S.C., et al. (2012), *A Call for transparent reporting to optimize the predictive value of preclinical research*, Nature 490:187-191.**
- To improve reproducibility and potential translation of animal data into new treatments for patients:
    - Preclinical animal studies should follow standardised protocols such as those outlined in the **Ludolph et al. (2010), *Guidelines for preclinical animal research in ALS/MND: A consensus meeting*, Amyotrophic Lateral Sclerosis, 11:1-2,38-45.**
    - Applications incorporating additional studies in human tissues and/or iPSC lines to strengthen animal data are encouraged and will be looked upon favourably.
    - Projects using **multiple preclinical disease models/strains** (e.g. SOD1, cytoplasmic mislocalised TDP43, C9orf72, etc) to help demonstrate possible replication of effect of treatment and/or improved application of results will be looked upon favourably.
    - Projects incorporating the use of **biomarkers** to assess and confirm target engagement of the lead compound and to help establish potential drug efficacy signals are strongly encouraged.
    - Riluzole therapy is widely used within the human MND/ALS patient population. Therefore, all preclinical efficacy, PK, and toxicology studies of new compounds supported by these Drug Development Grants **should include experiments with and without riluzole as an add-on therapy, to assess for any possible drug interactions**.
    - Over 98% of compounds intended for therapeutic use in the CNS never reach the market because of their inherent inability to cross the Blood Brain Barrier (BBB). Therefore, it is critical to determine the BBB permeability of CNS drug candidates early in drug discovery, so that candidates with poor CNS penetration can be excluded or structurally modified, and promising candidates can be accelerated through the development process. **Applications should include details of BBB permeability** assessment and preferably will include 2 or more of the following where relevant:
        - *in vitro* BBB permeability assessment;
        - *in vivo* BBB permeability assessment; and
        - *in silico* BBB permeability assessment.

GRANT OUTLINE

New Therapeutic Development Grants: Supporting post-discovery, preclinical development of therapeutics for MND through a wide range of development activities – from validation of therapeutic leads to the submission of investigational new drug applications to regulatory bodies.

Applications supported by these grants must begin with identified lead compounds in hand.

- Applications must include any supporting preliminary data relevant to the phase(s) of the preclinical development process covered by the proposed research.
- Priorities for funding consideration include projects incorporating the following:
    - Secondary validation of lead compounds obtained from screening or by other means to demonstrate target selectivity and mechanism of action;
    - Optimisation of potency and pharmacological properties;
    - Studies on formulation and stability; and
    - *In vitro* and *in vivo* efficacy studies, ADME, BBB permeability assessment, toxicology, pharmacokinetics and pharmacodynamics studies for the development of pharmacological agents to the US Investigational New Drug (IND) and Australian TGA CTN application stage.
- Where possible, applications should include details for the design and implementation of full-scale current Good Manufacturing Practice (cGMP) production of the lead compound and the delivery systems for use in advanced preclinical and initial clinical trials.

Repurposing: Supporting hypothesis-driven drug repurposing efforts focused on new therapeutics for MND.

- Testing of compounds currently approved for other indications in established animal models of MND.
- Applications incorporating additional studies in human tissues and/or iPSC lines to strengthen animal data are encouraged.
- Proposals should be hypothesis driven and drugs chosen for repurposing testing should either:
    - target a mechanism of action(s) common to both diseases; or
    - target a new or novel mechanism of action (supported by appropriate preliminary data or evidence).

The preclinical drug development process may require resources beyond those available at a single organisation. Therefore, these grants are open to investigators participating in synergistic collaborations focused on testing and developing lead agents for the treatment of MND. Collaborations should be dedicated to a single, synergistic preclinical development project or study rather than an additive set of subprojects (i.e. the combined efforts of the collaboration must provide greater benefit than the sum of individual research initiatives).

GRANT OUTLINE

- If a collaboration is proposed, letters confirming/supporting the collaboration are required. If the collaboration is multi-organisational, participating organisations will ensure the success of the collaboration by resolving potential intellectual and material property issues and by removing organisational barriers that might interfere with achieving high levels of cooperation. Details on these processes must be included in the application.

- Biotechnology or pharmaceutical companies are encouraged to apply. Whether a biotechnology or pharmaceutical company applies for these grants as an individual applicant or as part of a collaboration, the company is expected to leverage its own resources to complement the funding provided by these grants.

- Applicants with limited MND research experience are strongly encouraged to collaborate with those having more substantial expertise in MND research and/or MND model systems.

- A full detailed budget for the proposed project is to be included with a year-to-year breakdown. The contributions (if applicable) from other funding sources should also be included.

- Applications for a Phase I clinical trial must include Project/Study Milestones that align with the proposed budget. Milestones can include, but are not limited to:
    - Human Research Ethics Committee (HREC) approval for the study;
    - GMP manufacture/stability set up;
    - Completion of GMP stability;
    - Clinical Trial commencement;
    - Recruitment of 10th trial participant;
    - Completion of all study visits and database lock;
    - Final report received by FightMND.

Note: Meeting milestones is an important requirement for Phase I clinical trials supported by FightMND Drug Development 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.

Where relevant, applications for projects must include a realistic timeline of future development to a Phase I trial. Projects demonstrating a true bench-to-bedside applicability between 24 – 36 months will be considered favourably.

FUNDING - SCOPE AND CRITERIA

The scope and criteria for funding is as outlined below:

- The maximum period of grant funding for Drug Development projects is 3 years.
- The maximum allowable direct cost for Drug Development Research Grants is **$1,000,000** AUD. FightMND does not provide funding for indirect costs.
- More cost-effective studies that do not request the full available funding amount are encouraged.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum of 3 years with appropriate justification.
- Timelines must be clearly described (Gantt chart format) with clear go/no-go milestones.
- Payment structure will be based on achievement of milestones, which will be finalised jointly with the investigators and the FightMND scientific advisory board if the project is approved for funding. A minimum of 6-monthly progress reports will be required.
- Payment structure will be based on achievement of milestones, which will be finalised jointly with the investigators and the FightMND scientific advisory board if the project is approved for funding. A minimum of 6-monthly progress reports will be required.
- Continuity of funding, in 6-monthly instalments, will be depend on a satisfactory comprehensive progress report from the PI and an itemised financial report at the end of each year. Regardless of the period of funding proposed, the application must not exceed the maximum allowable costs.
- For Phase I clinical trials, continuity of funding is dependent on milestone achievement. Future payment instalments will not be made until the relevant milestone has been achieved.
- The research project can commence immediately upon receipt of a signed Grant Agreement, and must commence within 3 months of the receipt of a signed Grant Agreement.
- Travel costs of up to $5,000 AUD per year to attend and/or present at scientific/technical meetings are allowed within the budget.
- Investigators at all academic levels are eligible to submit applications.
- The applicant must be the Primary Investigator (PI) and have the lead role in directing the project. In addition:
    - The level of contribution and role of the PI and other co-Investigators (CIs) must be clearly defined on the application cover sheet;
    - The PI may be based internationally/outside of Australia;
    - A CV must be provided for all investigators (3 pages max. for each Investigator); and
    - Applications involving collaborations with MND researchers within Australia will be looked upon favourably.

FUNDING

- Salaries for the PI or co-Investigators will not be supported (unless they are within 5-years of being awarded their PhD).
- Capital equipment, depreciation, or maintenance of equipment will not be funded by FightMND Drug Development Grants.
- Cash and in-kind co-contributions from applicants will be viewed favourably.
- Any other actual or proposed sources of funding to support the project must be disclosed.
- FightMND reserves the right of refusal of any project applications that it deems fall outside these criteria.
- Successful applicants are encouraged to provide regular information or feedback on their research to be circulated by FightMND for MND patients and carers. The Primary Investigator [or co-Investigator(s)] is required to present progress of the Drug Development Project at research symposiums annually, and to FightMND donors and supporters at a FightMND research symposiums to be conducted in Melbourne (dates to be confirmed).
- It is an expectation of successful applicants that project findings are to be published in appropriate peer-reviewed academic and professional journals with details sent to FightMND. Costs to enable open access for publications may be included in the budget.

REPORTING

Funding recipients will be required to submit reports on a regular basis. 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
Milestone Notification for Phase I Clinical Trials	As agreed 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 (Melbourne, Vic)	Biennially	During FightMND Research Symposium

*These reports will be used to assess whether the project 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 Drug Development Research Grant.

PRIVACY, CONFLICT OF INTEREST

PRIVACY AND CONFIDENTIALITY

All information contained in applications forwarded to FightMND will be regarded as confidential. 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 members of the FightMND Scientific Advisory Panel (SAP), independent reviewers/assessors requested by the SAP to provide advice on the applications, the FightMND Board, and relevant employees of FightMND involved in the research grant process.

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

CONFLICT OF INTEREST – SAP MEMBERS

FightMND requires its evaluation committee (SAP) members to act in an ethical manner, declare conflicts of interest, and withdraw from considering applications where such conflict does or may exist.

ACKNOWLEDGEMENT OF SUPPORT

Successful applicants are required to acknowledge FightMND in any publications, public announcements, media, and scientific 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

Please use the template below as an example of the format required in submission of your letter of intent. Letters of intent should be submitted with a minimum size 12 font (calibri preferred), one (1) cm margins and must not exceed 3 pages. A brief CV of the Principal Investigator (2 pages max.) should also be submitted with the letter of intent for consideration.

Project title:
Primary Investigator:
Institution:
Estimated budget:
Duration of project:

Briefly describe any relevant preclinical or clinical evidence that supports the study rationale:		
Project aims:		
Briefly describe the study design:		
Where applicable, list the MND models that will be utilised in the proposal:		
Indicate how the aims of this project will help translate therapeutics for the treatment of MND/ALS to the clinic:		
Number of subjects to be enrolled (if applicable):		
Number of Australian Clinical Sites (if applicable):		
Is the lead candidate a new or a re-purposed therapeutic?		
Does the application include the use of a biomarker(s) to confirm target engagement of the lead compound?	YES	NO
Does the application address the blood-brain-barrier permeability of the lead compound?	YES	NO

SUBMISSION GUIDELINES

Please provide a details of each of the collaborators involved in the project including:

- Name
- Affiliations
- Specific role relevant to project aims

The total budget including indirect costs cannot exceed AUD $1,000,000 (unless additional funding sources are available outside of these grants). FightMND does not provide funding for indirect or overhead costs, or on-costs, of an Administering Institution.

SUBMISSION GUIDELINES

FULL APPLICATION

Should you be invited to submit a full application, submissions must include the following:

- **Cover sheet** (see page 18).
- **A 50 word lay summary of the project** suitable for media release if the application is successful.
- **A 250 word lay summary of the project** suitable for publication on the FightMND website and newsletter if the application is successful.
    - Provide background information necessary for readers without scientific or medical training to understand the rationale and feasibility of the proposed Drug Development project. It should also clearly describe the scientific objective the project is designed to achieve.
    - Describe the ultimate applicability of the research (in lay terms):
        - What type of MND patients (e.g. Sporadic vs Familial) will it help and how it will help them (e.g. symptom control vs. disease progression)?
        - What are the potential clinical applications, benefits, and risks?
        - What is the projected time to achieve a patient-related outcome?
        - What are the likely contributions of this study in advancing the development of a therapy for MND?
- **Research proposal for project** (8 pages max., font size 12 – calibri preferred, minimum 1 cm margins). Provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the project including:
    - Aims of the project stating clearly and concisely which hypotheses are being tested, and the applicability of results to the further development of a potential treatment for MND;
    - Background;
    - Preliminary and supporting data relevant to the phase(s) of the preclinical development as required;
    - Research plan and timeline:
        - Provide a detailed outline of the research for the full period of performance, including clear go/no-go milestones with justifications.
        - Provision of an accompanying Gantt diagram outlining the proposed timeline.
        - **For animal studies**:
            - Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives, and where appropriate, the study's relevance to sporadic human MND biology;
            - Summarise the procedures to be conducted and describe how the study will be controlled;
            - To further support the advancement of a particular therapeutic candidate, studies should aim to demonstrate beneficial effects

across a range of outcomes, including motor or cognitive function, neurophysiology, histopathology, and survival when using *in vivo* models of MND;

- Describe the randomisation and blinding procedures for the study, and any other measures to be taken to minimise the effects of subjective bias during animal treatment and assessment of results. Provide justification if randomisation and/or blinding will not be utilised;
- Provide a sample size estimate for each arm and the method by which it was derived, including power analysis calculations;
- Describe how data will be handled – including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s); and
- Attach proof of ethics approval for all proposed animal studies.

- **In studies utilising iPSC lines**, investigators should:
  - Incorporate uniform differentiation protocols to improve reproducibility;
  - Use cell lines from a sufficient number of participants per group for studies comparing disease and control;
  - Use genetically matched (isogenic) mutation-corrected lines when applicable (with rigorous quality control including karyotyping) to control for variability due to intrinsic genetic background of subjects; and
  - Address the limitations of and issues related to the immature/foetal nature of the derived experimental tissue and how/if these will be addressed.
- Address potential pitfalls and problem areas within the scope of the proposed project and present alternative methods and approaches.

- **References** (2 pages max.).
- **Impact Statement** (1 page max.). Describe:
  - How the project will make an important contribution to MND therapeutic development; and
  - In general terms how the outcomes of the project, if successful, will be translated to the clinic and made available to MND patients.
- **Transition Plan** (3 pages max.). The applicant:
  - Must demonstrate that they have access to all intellectual property rights necessary for development and commercialisation.
  - Where possible, should describe/discuss the methods and strategies proposed to move the lead compound(s) into the next phase of development (e.g. clinical trials, commercialisation, and/or delivery to the patient population) after successful completion of this project.

The transition plan should include components listed below (where relevant):

- The development and/or commercialisation strategy;
- Details of the funding strategy to transition to the next level of development and/or commercialisation (e.g. partners, pharma, internal/external funding opportunities to be applied for);
- A schedule and milestones for transitioning to the next phase of development, including a Gantt chart; and
- A risk analysis for cost, schedule, manufacturability, and sustainability moving forward.

- **Budget Justification** including a year-by-year breakdown (1 page max.).

  Budget items can include:

  - Salaries for team members;
  - Salary oncostsif itemised (e.g. superannuation, payroll tax, work cover);
  - Direct research costs (e.g. regents and consumables etc.);
  - Travel costs for one team member to attend relevant ALS/MND scientific meetings to present the findings of the project each year for the duration of the grant (maximum $5,000 per year); and
  - Costs to enable open access for publications within 6 months of publication can be included in the project budget. All other manuscript publication costs should be the responsibility of the Administering Institution and/or Primary Investigator.

  Budget items cannot include:

  - Salaries for Primary Investigators or co-Investigators (unless they are an early-career researcher within 7 years of PhD being awarded);
  - Equipment items;
  - Computers; and
  - Indirect, overhead or oncosts of the Institution.

- **Milestones** (1/2 page max. Phase I Clinical Trials only).

  Phase I clinical trial applications must include Project/Study Milestones that align with the proposed budget (see Grant Outline section on page 7). Note: Continuity of funding for Phase I clinical trials is dependent on milestone achievement. Please consider this when planning your study, milestones and budget.

- **Other sources of funding to support the project should be disclosed.**
- **Declaration and details of research funding from other sources (actual or proposed) that relate to the Drug Development Grant's hypothesis, aims and research plan.**

  Include:

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

SUBMISSION GUIDELINES

- **Curriculum vitae of all Investigators** (3 pages max. per Investigator).

  Please 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.
- **Collaboration Plan** (2 pages max.).
  - Name(s) of the Department(s) and Institution(s) where the Drug Development project will be carried out, and nomination of the Primary Department/Institution.
  - Suitability of the Department and Institution for supporting the Drug Development Grant and outlined projects should be clearly outlined.
  - Describe the specific role(s) of each collaborator in the proposed project and evidence that they are equipped to fulfil the role.
  - If the project involves a multi-organisational collaboration, participating organisations will ensure the success of the collaboration by resolving potential intellectual and material property issues and by removing organisational barriers that might interfere with achieving high levels of cooperation. Details on these processes should be included in the application, including all details of intellectual property ownership, and a description of any appropriate intellectual and material property plans amongst collaborating organisations.
- **A letter of support from the Administering/Sponsoring Institution(s)** stating their suitability and role in advancing the Drug Development Project's progress and success, and confirming that laboratory space will be provided for the duration of the project (1 page max.).

HOW TO SUBMIT

All applicants are asked to submit their applications electronically (file size not to exceed 5MB) as a PDF. Drug Development Grant applications should be forwarded to Dr Davor Stanic, FightMND Research Co-ordinator, at researchgrants@fightmnd.org.au.

APPLICATION COVER SHEET

All applications must be accompanied by a Cover sheet like the one provided below.

1	Project Title	
2	Title, name and qualifications of Primary Investigator (PI)	
3	Key words (4 minimum)	
4	Email address of PI	
5	Mobile phone No. of PI	
6a	Name, Institution, % contribution to project and role of PI	
6b	Name, Institution, % contribution to project and role of co-investigator (CI)	
6c	Name, institution, % contribution to project and role of co-investigator (add rows if more than 2 co-Investigators)	
7	Administering Organisation/Sponsoring Institution administering the grant	
8	Name of research grant administrator for (7)	
9	Contact details for (8)	
10	Total Budget Estimates for each year	Year 1 $ Year 2 $ Year 3 $ TOTAL - $
11	A 50 word max. lay summary of the project suitable for media release if the application is successful.	
12	Summary/Lay description (250 words max. – use separate page if required). Describe in terms and language applicable to the general public, the overall aims and expected outcomes of this project.	

DRUG DEVELOPMENT RESEARCH GRANTS
TERMS & CONDITIONS

All communication concerning Drug Development Grant applications and administration should be addressed to the FightMND Research Co-ordinator, Dr Davor Stanic, by email to researchgrants@fightmnd.org.au.

1. FUNDING ARRANGEMENTS

1.1. FightMND Drug Development Grants are time-limited, and applicants should ensure that proper consideration is given to this in the proposal. When the project is approved in principle, the initial sum awarded by FightMND will be for the first six (6) months only. Approval of funding for subsequent invoices at six (6) monthly intervals will be subject to availability of funds, the receipt, from the grantee, of satisfactory project progress and financial reports, and achievement of agreed milestones if the Drug Development Grant awarded is for a Phase I clinical trial. Members of FightMND, the SAP and Board will review progress reports to decide outcomes.

1.2. 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 Dr Davor Stanic, FightMND Research Co-ordinator, at least eight weeks prior to the original completion date at researchgrants@fightmnd.org.au.

1.3. The value of the Drug Development Grant is up to a total of $1,000,000 AUD for project performance of up to three (3) years.

1.4. FightMND will not meet indirect or overhead costs or on-costs of the Administering Institution, such as: general travel, finance services, staff facilities, staff 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).

1.5. Conference attendance: FightMND will allow up to $5,000 per annum towards the cost of relevant conference attendance and participation by the primary investigator 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. The investigators are encouraged to present their work. The primary investigator is expected to attend at least one relevant meeting per year.

1.6. Payment of instalments is conditional on receipt and approval of satisfactory project progress and financial reports, and achievement of agreed milestones if the Drug Development Grant awarded is for a Phase I clinical trial (see condition 1.1 and 15.1).

1.7. Funding from other sources: financial support for clearly defined 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.

2. EQUIPMENT

2.1. In general, FightMND will not fund any equipment purchase as part of this Drug Development Grant. However, in the exceptional circumstance where FightMND approves the purchase of equipment using FightMND funds, and the Primary Investigator and Administering Institution has received written approval from FightMND for the purchase of equipment using FightMND funds, the equipment purchased within the terms of the Grant must not be modified or removed from the Grantee's institution without FightMND's permission. Should the Primary Investigator move to another institution during the tenure of the Grant, FightMND reserves the right that the equipment be transferred with him/her following negotiation.

3. ETHICAL CONSIDERATIONS.

3.1. It is the responsibility of the Applicants have ethical committee approval for all or part of the planned research. This should ideally be in place at the time of applying for funding.

3.2. Approvals must be received, and copies provided to FightMND upon request, prior to the Drug Development Grant 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 qualified Investigator, ideally obtained prior to the absence. The grantee oran approved representative of the Administering Institution must apply to and notify the FightMND Research Co-ordinator, Dr Davor Stanic, at researchgrants@fightmnd.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 STAFF

5.1. FightMND does not act as an employer and, therefore, in all cases where financial support is provided for the employment of staff, the Administering or Host 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 dministering or Host institution against a claim for compensation or against any claims for which the Institution may be liable as an employer or otherwise.

6. STAFF MANAGEMENT RESPONSIBILITY

The Administering Institution must accept full responsibility for:

6.1. The management, monitoring and control for all staff (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 staff recruited to work on the FightMND-supported project continues beyond the defined period of the Grant, the Administering 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 defined grant period.

8. EMPLOYMENT TERM CONTRACTS

8.1. Where members of staff have been under contract to the Administering Institution prior to the activation of the FightMND Drug Development 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 offered must not extend beyond the termination of the Drug Development Grant (unless the Administering Institution wishes to extend the contract at its own expense).

9. MATERNITY AND OTHER LONG-TERM LEAVE

9.1. The Administering 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 Drug Development Grant period. Long-term leave may include maternity, paternity or long-term sick leave.

9.2. Maternity or paternity leave is the responsibility of the Administering Institution employing staff undertaking a FightMND project. Leave will be provided according to the Administering Institution's local terms and conditions of employment. The costs of such leave are the responsibility of the Administering 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 Drug Development 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 Drug Development Grant Primary Investigator oran approved representative of the Administering Institution should contact FightMND as soon as possible to discuss the situation with the Research Co-ordinator.

10. ACTIVATION OF AN AWARDED DRUG DEVELOPMENT GRANT

10.1. Drug Development 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 Amendment Application* completed, and a new start date agreed (see Terms and Conditions 11.2). If necessary, a revised Grant Agreement will need to be completed and returned.

10.2. If the project does not start within three (3) months of the original agreed start date, FightMND may withdraw the Drug Development Grant offer. The grantee 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 (if required) is in place prior to the project 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 DRUG DEVELOPMENT 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 complete a *Grant Agreement Amendment Application* detailing any and all proposed changes to the project. Applications must be submitted (where possible) at least eight weeks prior to the changes taking place, and submitted for approval to the FightMND Research Co-ordinator, Dr Davor Stanic, by email 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 Drug Development 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 DRUG DEVELOPMENT GRANT

12.1. FightMND reserves the right to change the Terms and Conditions of Drug Development Grants at any time. If this occurs during the lifetime of a Drug Development 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 DRUG DEVELOPMENT GRANT

13.1. FightMND reserves the right to terminate an awarded Drug Development 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 project. The Drug Development Grant Primary Investigator or an approved representative of the Administering 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, or serious and unresolvable problems identified by a site visit; and/or
- Work has ceased on the 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 a Drug Development Grant.

13.2. If a Drug Development 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 Drug Development Grant remaining to be paid at the time of its termination.

13.3. In the event of work being discontinued by the Administering 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 DRUG DEVELOPMENT GRANT

14.1. It is the responsibility of the Primary Investigator to apply for further support before the end of the Drug Development 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 Drug Development Grant start date, as stated on the executed Drug Development Grant Agreement (see Terms and Conditions 1.1). 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 two pages on project progress;
- **Final report:** required within six weeks after completion of the Drug Development Grant project. A detailed final report covering the whole project 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; and
- **FightMND Research Symposium:** the Primary Investigator is required to present progress of the Drug Development project annually, and at the FightMND Research Symposium.

- **Notification of Milestone achievement** (Phase I Clinical Trial Grants only)**:** The FightMND Research Co-ordinator, Dr Davor Stanic, should be notified when the Clinical Trial has achieved agreed milestones, by email to researchgrants@fightmnd.org.au.

15.2. The final instalment of the Grant will be paid only after receipt of the final report and its approval by FightMND. Payment may be delayed further if reports are not submitted on time and/or if clarification 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 laboratory during the period of the Drug Development 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 Drug Development Grant.

17. PUBLICATIONS, PRESENTATIONS, ACKNOWLEDGMENTS AND PUBLICITY

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

17.2. Grantees must inform FightMND immediately when results from FightMND-funded research are accepted for publication or presentation. The grantee 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 Drug Development 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 $250 per Drug Development 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 Drug Development 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 FightMND's Research Co-ordinator Dr Davor Stanic by email to researchgrants@fightmnd.org.au, Research Director Dr Bec Sheean at research@fightmnd.org.au and Communications Manager Andrew Holmes at andrew@fightmnd.org.au at least five working days in advance of any publicity arising from research wholly or co-funded by a FightMND Drug Development 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 our 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.fightmnd.org.au.

17.8. Grantees must ensure that FightMND's support is acknowledged in all publications, presentations and similar communications. It is essential for Drug Development grantees to acknowledge that their research has been supported wholly or in part by FightMND, either in the text or in a footnote. The Drug Development 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 Research Director, Dr Bec Sheean, at research@fightmnd.org.au and Communications Manager, Andrew Holmes, at andrew@fightmnd.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 Institution must obtain the written consent of FightMND before taking any steps to exploit the results commercially. The Grantee and Administering 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 Drug Development 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 Drug Development 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 Drug Development Grant project at scientific 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 reflecting the work of FightMND for its wide-ranging communications and fundraising activities.

21. SCIENTIFIC INTEGRITY

21.1. In the rare event of scientific 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 scientific fraud. If fraud should be proven the Drug Development 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 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 benefit. 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 different categories:

- Copyright: protects written, dramatic and artistic work, software, films, 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 Clinical Trial 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 identification, 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 staff and sub-contractors), are employed or retained on terms that vest in the institution all intellectual property arising from funding by FightMND.

APPENDIX 1

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 offered a time-limited opportunity to take out a revenue generating licence.

1.5. The Administering Institution and the Clinical Trial 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 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 30 days of receiving the notification from the Administering Institution, and prior to the Administering Institution applying for registration of any Commercial IP, FightMND will advise the Administering Institution in writing which one of the following financial arrangements will apply in relation to commercialisation of the Commercial IP:

I. All of the costs associated with commercialising of the Commercial 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 Commercial IP (after all of the Administering Institution's costs associated with commercialising the Commercial IP have first 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 Clinical Trial Grant funding provided under this agreement multiplied by five (5).

II. Ten per cent (10%) of the costs associated with commercialising the Commercial 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 Commercial IP (after all the Administering Institution's costs associated with commercialising the Commercial IP have first 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 Commercial 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 provide details to, and obtain prior written approval from, FightMND.