2020

RESEARCH GRANTS

FIGHT MND.

IT TAKES PEOPLE

DRUG DEVELOPMENT

RESEARCH GRANTS

CONTENTS

FIGHT MND.
IT TAKES PEOPLE

ACRONYMS & DEFINITIONS

Administering Organisation: 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.

Administering Office/Grants Officer: Person responsible for receiving and administering funds from the Administering Organisation.

Applicant: Researcher leading the research - the Principal Investigator (PI) who is responsible for the overall direction of the project, leading and supporting Associate/Co-investigators (CIs), completion and lodgment of the application and progress and reporting on the project. Where the project involves multi-site research, the Applicant must obtain written commitment from all Heads of Departments of collaborative partners not within the Administering Organisation, and must assume responsibility for undertaking and completing the activities outlined in the application.

Associate/Co-investigator(s): responsible for carrying out some aspects of the research under the guidance and leadership of the Applicant/Principle Investigator.

Collaboration and Collaborator/Collaborative Partner(s): All people and organisations involved in the research 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. Associate/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 & Services Tax: Goods and Services Tax 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 organisation's GST status.

Motor Neurone Disease (MND): For the purposes of these grants and project funding, 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: is 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 pre-clinical 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 pre-clinical research, development and assessment of therapeutics for MND/ALS through to (and including) completion of Phase I clinical trials.

Applications Open: November 1 2019

Letter of Intent due: January 17 2020

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

Invitation to submit full application: February 3 2020

Full application due: April 1 2020

Recipients Notified: July 2020

FightMND is pleased to announce a call for Drug Development Grant applications to support pre-clinical translational research through to and including Phase I clinical trials. Grant applications will be considered for:

- **New Therapeutic Development Grants:** Supporting post-discovery, pre-clinical 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.

These 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).

Such 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 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 pre-clinical 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;:
  - Pre-clinical 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 pre-clinical 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.
  - A preference for projects incorporating the use of **biomarkers** to assess and confirm target engagement of the lead compound and to help establish potential drug efficacy signals and are strongly encouraged.
  - Riluzole therapy is widely used within the human MND/ALS patient population. Therefore all preclinical efficacy, PK, and toxicology studies supported by these grants of new compounds **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 poor CNS candidates can be excluded or structurally modified, and promising CNS 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, pre-clinical 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.

- Applications must include any supporting preliminary data relevant to the phase(s) of the pre-clinical 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 iPS 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 pre-clinical 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 should 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 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.

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

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.

- Time-lines 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.

- Continuity of funding year-to-year 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.

- The research project can commence immediately when awarded, and must commence within 6 months of the time of the notification of the award.

- 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.

FUNDING

- 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 sheet.
  - The PI may be based internationally/outside of Australia.
  - A CV must be provided for all investigators.
  - Applications involving collaborations with MND researchers within Australia will be looked upon favourably.

- Salaries for the PI or co-investigators will not be supported.

- 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 will be required to present the planned research project/progress to FightMND donors and supporters at a research symposium to be conducted in Melbourne yearly following funding announcements (date 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.

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
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)	Annually	At commencement of funding and every 12 months from receipt of funds.

*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 grant. Such disclosure includes but is not limited to members of the FightMND Scientific Advisory Panel (SAP), independent readers/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 the funded grants will involve a dissemination of information to the public about the general nature of the funded grants.

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. Letter of intent submissions should be submitted with a minimum size 12 font, 1 cm margins and must not exceed 3 pages. A brief CV of the Principal Investigator should also be submitted with the letter of intent for consideration.

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

Briefly describe any relevant pre-clinical 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 costs.

SUBMISSION GUIDELINES

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

- **Cover sheet**
- **Lay description/Summary**
- A 50 word lay summary of the project suitable for media release if the application is successful.
- A 250 word summary of the project suitable for 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 readily 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):
        i. 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)
        ii. What are the potential clinical applications, benefits, and risks?
        iii. What is the projected time to achieve a patient-related outcome?
        iv. What are the likely contributions of this study in advancing the development of a therapy for MND?
- **Research proposal for project** (maximum 8 pages, font size 12, 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:
        i. Provide a detailed outline of the research for the full period of performance, including clear go/no-go milestones with justifications; and
        ii. Provision of an accompanying Gantt diagram outlining this proposed timeline.
        iii. 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).
- Attach proof of ethics approval for all proposed animal studies.

iv. **In studies utilising iPS 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.
- Address the limitations of and issues related to the immature/foetal nature of the derived experimental tissue and how/if these will be addressed.

v. Address potential pitfalls and problem areas within the scope of the proposed project and present alternative methods and approaches.

- **References:** (maximum 2 pages).
- **Impact Statement** (maximum 1 page):
  - Describe how the project will make an important contribution to MND therapeutic development.
  - Describe 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 maximum):
  - The applicant must demonstrate that they have access to all intellectual property rights necessary for development and commercialisation.
  - Where possible, the application 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.
    - A risk analysis for cost, schedule, manufacturability, and sustainability moving forward.

SUBMISSION GUIDELINES

- **Budget Justification** including a year-by-year breakdown (maximum 1 page). **Budget items can include**:
  - Salary for team members;
  - 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
  - Manuscript publication costs.

  Budget items cannot include:

  - Salary for chief/primary investigators.
  - Large equipment items.
  - Computers.
  - Indirect or overhead costs.

- **Other sources of funding to support the project should be disclosed.**

- **Curriculum vitae of all investigators** (maximum 3 pages each). 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** (maximum 2 pages)
  - Name(s) of the institution(s) where the work will be carried out
  - State in which department and which institution this project will primarily be carried out. A letter from the sponsoring institution(s) confirming that laboratory space will be provided for the duration of the project is required.
  - 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.

HOW TO SUBMIT

All applicants are asked to submit their applications electronically (file size not to exceed 5MB) in **Word doc** or **PDF** form (size 12 font). Drug Development Research Grant applications should be forwarded to Dr Davor Stanic, Research Coordinator, 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 APPLICANT	
3	KEY WORDS	
4	EMAIL ADDRESS OF APPLICANT	
5	MOBILE PHONE NO. OF APPLICANT	
6a	NAME, INSTITUTION, % CONTRIBUTION AND ROLE OF PRIMARY INVESTIGATOR (PI)	
6b	NAME, INSTITUTION, % CONTRIBUTION AND ROLE OF CO-INVESTIGATOR (CI)	
6c	NAME, INSTITUTION, % CONTRIBUTION AND ROLE OF CO-INVESTIGATOR (CI)	
6d	NAME, INSTITUTION, % CONTRIBUTION AND ROLE OF CO-INVESTIGATOR (CI)	
6e	NAME, INSTITUTION, % CONTRIBUTION AND ROLE OF CO-INVESTIGATOR (CI)	
7	ADMINISTERING ORGANISATION/ SPONSORING INSTITUTION ADMINISTERING	
8	NAME OF RESEARCH GRANT ADMINISTRATOR FOR (6)	
9	CONTACT DETAILS FOR (7)	
10	TOTAL BUDGET ESTIMATES FOR EACH YEAR	

TERMS & CONDITIONS

DRUG DEVELOPMENT RESEARCH GRANTS
TERMS & CONDITIONS

All communication concerning applications and administration should be addressed to Dr Davor Stanic, Research Coordinator, at researchgrants@fightmnd.org.au.

1. FUNDING ARRANGEMENTS

1.1 These Drug Development Research grants are time-limited and applicants should ensure that proper consideration is given to this in the . 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 and the receipt, from the grantee, of satisfactory project progress and financial reports. Members of the Foundation, 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 ResearchCoordinator, at researchgrants@fightmnd.org.au at least eight weeks prior to the original completion date.

1.3 The value of Drug Development Grants is for up to $1,000,000 AUD total for a period of 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.

1.5 **Conference attendance:** FightMND will allow up to $5,000 per annum towards the cost of relevant conference attendance by the primary investigator to be drawn from the award total sum. 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 if possible. The primary investigator is expected to attend at least one relevant meeting per year.

1.6 Payment of installments is conditional on receipt and approval of satisfactory project progress and financial reports (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, following written approval from FightMND, equipment purchased with FightMND funds 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 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 either individual requires written agreement to continue the research under the direction of another qualified investigator, ideally obtained prior to the absence. The grantee or the Head of Department must apply to and notify the FightMND ResearchCoordinator, 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 grant condition 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 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 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 host 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 bye 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 period of the award, the host institution will be solely responsible for all costs beyond the period of the award. 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 host institution prior to the activation of the FightMND award, 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 grant (unless the host institution wishes to extend the contract at its own expense).

9 MATERNITY AND OTHER LONG-TERM LEAVE

9.1 The host 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 award period. Long-term leave may include maternity, paternity or long-term sick leave.

9.2 Maternity or paternity leave is the responsibility of the host institution employing staff undertaking a FightMND project. Leave will be provided according to the host institution's local terms and conditions of employment. The costs of such leave are the responsibility of the host 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 award holder should inform FightMND of the dates in advance. This will enable discussion to decide whether the award should be suspended for the period of absence until full-time employment can be resumed (see grant conditions 4 and 11.2). If unplanned long-term leave occurs, the award holder or the Head of Department should contact FightMND as soon as possible to discuss the situation with the Research Director.

10 ACTIVATION OF 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 form has been returned, FightMND must be informed at once, a *Grant Amendment Application* completed, and a new start date agreed (see grant condition 11.2). If necessary, a revised Grant Agreement form 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 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 grantee 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 AWARD

11.1 Reallocation of funds from one expense heading to another, as detailed in the grant agreement, requires written permission from FightMND.

11.2 Grantees will be required to complete an *Grant 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 FightMND Research Coordinator Dr Davor Stanic at researchgrants@fightmnd.org.au. FightMND must be kept informed at all time of any changes to the original grant.

11.3 Any request for major changes in the terms of the award, e.g. for additional staff or equipment, 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 AWARD

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 grant, the revised Terms and Conditions may be applied in place of those issued at the time of the original 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 AWARD

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 award was made.
- If the project has not started within three months of the agreed start date.
- The work is diverging markedly from the original approved project. Grant holders must inform FightMND immediately when they are aware of a change of direction (see grant condition 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.
- Work has stopped on the grant, or the Investigator has ceased to be actively involved in the project. FightMND must be informed immediately if the situation arises (see award condition 11.2).

FightMND will endeavour to give 60 days prior notice before termination of a Drug Development 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 host 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 AWARDS

14.1 It is the responsibility of the Principal Investigator to apply for further support before the end of the award 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 grant condition 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 Principal Investigator is required to submit the following reports:

- **Annual progress reports:** due every 12 months from the start date, as stated on the executed agreement (see grant condition 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 project completion. 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.
- **FightMND Research Symposium:** the Principal Investigator is required to present progress of the project annually at the FightMND Research Symposium.

15.2 The final installment of the award 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 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 project to discuss progress and welcomes invitations to do so.

16.2 The grantee 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 The grantee may be asked to take part in FightMND communication projects such as video content to help facilitate feedback to the Foundation’s donors on outcomes related to the grant.

TERMS & CONDITIONS

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 after conclusion of the Drug Development project (subject to condition 18). FightMND and the grantee jointly undertake to notify each other before published reference is made to the findings of the projec,t and to discuss 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 of awards from FightMND 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 of the paper. Publication costs 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 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 host 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 host institution must notify FightMND's 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 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 author must acknowledge our support and display our 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 the charity's website www.fightmnd.org.au

17.8 Grantees must ensure that the FightMND's support is acknowledged in all publications, presentations and similar communication. 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". Please note that researchers should consult our Research Director Dr Bec Sheean and Communications Manager Andrew Holmes at research@fightmnd.org.au and andrew@fightmnd.org.au, respectively, 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. 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 must obtain the written consent of FightMND before taking any steps to exploit the results commercially. The grantee 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 project at FightMND meetings, fundraising events and occasionally at other times by invitation.

19.2 There may be occasions where the grantee will be asked to present their work 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 the charity's 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 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 host 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 organization 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 grant awards 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 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.

1.4 The institution, grant holders and co-applicants 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 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 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 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 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 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 Project 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 recognized technology transfer company) to carry out its obligations with respect to IP, it must provide details to, and obtain prior written approval from FightMND.