2021

RESEARCH GRANTS

FIGHT MND.

IT TAKES PEOPLE

CLINICAL TRIAL GRANTS

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INTRODUCTION

FightMND Call for Proposals:

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

Applications Open: 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 Phase II/III clinical trial applications for novel, high-potential treatments in Motor Neurone Disease/Amyotrophic Lateral Sclerosis (MND/ALS) within the Australian Clinical Trials Consortium of hospitals.

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

Up to AUD $1,500,000 in support from FightMND is available per grant.

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

I. A pharmacodynamic marker that can measure whether the targeted pathway of interest has been affected;
II. A plan to collect samples for biomarker studies; and
III. Shown promising efficacy in at least two (2) MND disease models, one of which must be a representative model of human sporadic MND.

Industry partnership applications are strongly encouraged with shared funding proposals.

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

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

RESEARCH OBJECTIVES

The following research objectives govern the parameters of the trials:

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

Applications will be reviewed by FightMND-selected reviewers and the FightMND Grant Review Panel. The following will be considered in making funding decisions (see "Selection Criteria" on page 6 for further details):

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

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

Applicants may request the full AUD $1,500,000 in research support or may request a smaller amount depending on the appropriate needs of the proposed study. A maximum of 10% indirect costs is allowable and should be included in the AUD $1,500,000.

Industry partnership applications are strongly encouraged with shared funding proposals.

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

- Access to ten (10) clinical sites across Australia with access to between 50 – 350 MND patients at each site allowing for ease of enrolment;
- Project Management;
- Grants and Contracts Management;
- Biomarkers and bio-banking;

RESEARCH OBJECTIVES

- Start-up activities: site selection and feasibility, preparation and submission of Institutional Review Board/Ethics applications, Investigator meetings, contract negotiation;
- Site Initiation, monitoring, site management and close-out activities;
- Investigator meeting organisation, participation and close-out activities;
- Third party vendor selection and management;
- Study budget negotiation (sites and vendors) as well as budget management;
- Data management expertise with internal and external vendor capabilities;
- Biostatistician who is a specialist in neuroscience projects;
- Medical Monitoring capabilities;
- Utilising neurologists for this service as required;
- Data Safety Management Board selection, preparation of associated documentation, maintenance and assistance in report preparation;
- Regulatory assistance in preparation of IND packages, attendance at pre-IND, End of Phase 2 meetings and pre-NDA meetings;
- Medical writing, including Clinical Study Report preparation;
- Preparation of Standard Operating Procedures; and
- Training of site and study personnel in Good Clinical Practice.

SELECTION CRITERIA

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

SIGNIFICANCE

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

INNOVATION

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

DESIGN

- Is the conceptual framework, design, methods, and proposed analyses adequately developed, well-integrated, and appropriate to the aims of the study?
- Have potential problems and alternative strategies been considered?
- Is/are the primary endpoint(s) meaningful?

ENVIRONMENT/COLLABORATIVE POTENTIAL

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

INVESTIGATOR(S)/SPONSOR(S)

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

FIGHTMND POLICIES

FIGHTMND EQUITY VERSUS EFFICIENCY POLICY

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

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

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 Grant Review Panel, independent reviewers/assessors, the FightMND Board, and relevant employees of FightMND involved in the research grant process.

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

CONFLICT OF INTEREST – REVIEWERS

FightMND requires its independent reviewers and grant review panel 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), page margins of 1 cm, 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.

Project Title:
Principal Investigator and Institution:
Bio-statistician and Institution:
Pharmacologist (if applicable) and Institution:
Estimated direct costs for each year of funding: Year 1 $ Year 2 $ Year 3 $
Estimated direct costs for the study: $
Estimated per patient cost for the study: $ Per patient costs should be appropriately budgeted to ensure equity of recruitment across clinical sites in Australia

Please note that a maximum of 10% indirect costs may be included. The total budget including indirect costs cannot exceed AUD $1,500,000 (unless additional funding sources are available outside of these grants)

Primary Study aims:
Secondary aims (if any):
Briefly describe any relevant preclinical or clinical evidence that supports the study rationale:
Briefly describe the study design:

SUBMISSION GUIDELINES

Indicate how the primary aims of this preliminary study will help optimise the design of the eventual definitive phase III trial:		
Number of subjects to be enrolled: ~ Number of subjects to be enrolled in Australia: ~		
Number of Australian Clinical Sites:		
Describe how the intervention will be administered, including dose and duration as applicable. Do you have the drug and placebo in hand for the trial?		
Does this preliminary study include placebo or control group? If "yes" provide applicable rationale:	YES	NO
Does the trial drug have pre-clinical efficacy data in at least two (2) MND disease models - one of which MUST be a representative model of sporadic disease?	YES	NO
Describe the plan for sample collections and willingness to share samples with the MND research community:		
Describe the pharmacodynamic markers that will be used in the trial:		
Describe ethical and consent considerations of the proposed protocol:		
Participating pharmaceutical or device manufacturing company (if any):		
Do you hold or have you applied for an IND/IDE for this protocol? (Please note: it is NOT a requirement for trials in Australia)	YES	NO
List all core services that you are interested in utilising from a FightMND approved contract research organisation (CRO) - see "Research Objectives" page 4 - 5 for details:		

SUBMISSION GUIDELINES

FULL SUBMISSION

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

COVER SHEET (see page 12)

LAY DESCRIPTIONS/SUMMARIES

- 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 if the application is successful.

SUMMARY/OVERVIEW (1 page max.)

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

RESEARCH PLAN (7 pages max.)

- Background data and significance.
- Preliminary Studies.
- Research design and methods (study design; participant description, data to be collected; plan of analysis).
- Supportive documentation including a proposed timeline (e.g. Gantt chart) with milestones demonstrating that the trial will be conducted expeditiously.
- Appendix materials are allowed, including material to demonstrate that the treatment is ready for testing in humans. Please note, it is NOT a regulatory requirement for drugs to have an IND submission prior to human trials in Australia.

REFERENCES (2 pages max.)

BUDGET (2 pages max.)

- Applicants are strongly encouraged to contact FightMND in regard to budgeting and use of a FightMND approved Contract Research Organisation (CRO).
- Provide a full budget and budget justification. Note that continuity of funding is dependent on achieving study milestones (see below). Please consider this when planning the budget for your clinical trial application.
- Per patient costs **must** be included and clearly identifiable in the budget section of the application. Per patient costs should be appropriately budgeted to ensure equity of recruitment across clinical sites in Australia.

- All budgeted items must be listed in $AUD.

MILESTONES (0.5 page max.)

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

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

CURRICULUM VITAE OF ALL INVESTIGATORS (3 pages max. per Investigator).

Include:

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

DECLARATION OF OTHER FUNDING

- Declaration and details of research funding from other sources (actual or proposed) that relate to this clinical trial application must be stated and include:
  - Investigator, and Title of other Application;
  - Funding Source/Organisation and Application ID;
  - Role of Investigator on other Application;
  - Duration of other funding; and
  - Total amount requested.

HOW TO SUBMIT

The application deadlines are described in this guideline.

- All applicants are asked to submit their applications electronically (file size not to exceed 5MB) as a PDF (minimum size 12 font – calibri preferred, minimum 1cm page margins).
- The Clinical Trial Grant application should be submitted by email 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 Principal 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.	

REPORTING

PROPRIETARY RIGHTS

The Principal Investigator/Sponsor will maintain full control of scientific work and all corresponding responsibilities. A scope of work will be agreed upon by all parties prior to initiation of funding. If necessary, confidentiality agreements will be incorporated.

REPORTING REQUIREMENTS

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 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 clinical trial is proceeding satisfactorily, whether funds are being acquitted in accordance with the original application goals, and to ascertain the ongoing value of FightMND funding.

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

TERMS AND CONDITIONS

FIGHTMND PHASE II/III CLINICAL TRIAL GRANTS

TERMS AND CONDITIONS

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

1. PROPRIETARY RIGHTS

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

2. FUNDING ARRANGEMENTS

2.1. FightMND Clinical Trial Grants are time-limited, and applicants should ensure that proper consideration is given to this in the proposal. When the study is approved in principle, the initial sum awarded by FightMND will be for the 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 clinical trial progress and financial reports, and achievement of agreed milestones. Members of FightMND, its Cure Sub-Committee and Board will review progress reports to decide outcomes.

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

2.3. The value of the Phase II/III Clinical Trial Grant is up to a total of $1,500,000 AUD for performance of up to three (3) years.

2.4. FightMND will not meet indirect or overhead costs or on-costs of the Administering/Sponsoring 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).

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

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

2.7. 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.

3. ETHICAL CONSIDERATIONS.

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

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

4. PERSONAL DIRECTION OF THE PROJECT

4.1. It is expected that the Principal Investigator will be actively engaged in directing the project. Continued use of FightMND funds during a prolonged absence of the Principal Investigator requires written agreement to continue the research under the direction of another qualified Investigator, ideally obtained prior to the absence. The grantee or an approved representative of the Administering/Sponsoring Institution must apply to and notify Dr Davor Stanic, the FightMND Research Co-ordinator, 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 Sponsoring Institution undertakes to issue a contract of employment in accordance with any other relevant Act relating to the conditions of employment.

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

6. STAFF MANAGEMENT RESPONSIBILITY

The Administering/Sponsoring 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/Sponsoring Institution will be solely responsible for all costs beyond the period of the Grant. FightMND accepts no liability for contracts and costs extending beyond the defined grant period.

8. EMPLOYMENT TERM CONTRACTS

8.1. Where members of staff have been under contract to the Administering/Sponsoring Institution prior to the activation of the FightMND Clinical Trial 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 Clinical Trial Grant (unless the Administering/Sponsoring Institution wishes to extend the contract at its own expense).

9. MATERNITY AND OTHER LONG-TERM LEAVE

9.1. The Administering/Sponsoring institution will meet the cost of any long-term leave, other than holiday, and will ensure that all annual leave entitlement is taken within the Clinical Trial 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/Sponsoring Institution employing staff undertaking a FightMND project. Leave will be provided according to the Institution's local terms and conditions of employment. The costs of such leave are the responsibility of the Administering/Sponsoring Institution and are not provided for by FightMND.

9.3. If a FightMND funded employee is due to take any planned long-term leave, the Clinical Trial Grant Principal 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 Clinical Trial Grant Principal Investigator or an approved representative of the Administering/Sponsoring Institution should contact FightMND as soon as possible to discuss the situation with the Research Co-ordinator.

10. ACTIVATION OF AN AWARDED CLINICAL TRIAL GRANT

10.1. Clinical Trial 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 may need to be completed and returned.

10.2. If the Trial does not start within three (3) months of the original agreed start date, FightMND may withdraw the Clinical Trial 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 is in place prior to the trial starting. Payment of invoices will be delayed until evidence has been provided. It is the responsibility of the Principal 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 CLINICAL TRIAL 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 Trial. 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 Clinical Trial 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 CLINICAL TRIAL GRANT

12.1. FightMND reserves the right to change the Terms and Conditions of Clinical Trial Grants at any time. If this occurs during the lifetime of a Clinical Trial 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 Clinical Trial Grant.

13. EARLY TERMINATION OF AN AWARDED CLINICAL TRIAL GRANT

13.1. FightMND reserves the right to terminate an awarded Clinical Trial 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 Clinical Trial has not started within three months of the agreed start date;
- The work is diverging markedly from the original approved Trial. The Clinical Trial Grant Principal Investigator or an approved representative of the Administering/Sponsoring Institution must inform FightMND immediately when they are aware of a change of direction (see Terms and Conditions 11.2). There may, however, be circumstances in which the change is acceptable on scientific grounds;
- Failure to submit adequate progress reports, or serious and unresolvable problems identified by a site visit; and/or
- Work has ceased on the Trial/Grant, or the Principal 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 Clinical Trial Grant.

13.2. If a Clinical Trial 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 Clinical Trial Grant remaining to be paid at the time of its termination.

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

14. EXTENSION TO AN AWARDED CLINICAL TRIAL GRANT

14.1. It is the responsibility of the Principal Investigator to apply for further support before the end of the Clinical Trial 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 Principal Investigator is required to submit the following reports:

- **Annual progress reports:** due every 12 months from the Clinical Trial Grant start date, as stated on the executed Clinical Trial Grant Agreement (see Terms and Conditions 2.1). A short summary in language intelligible to the lay reader should also be submitted for possible use in FightMND publications and on our website;
- **Interim reports:** brief six-monthly reports of no more than two pages on project progress;
- **Final report:** required within six weeks after completion of the Clinical Trial Grant. A detailed final report covering the whole trial will be substituted for the annual report. In addition, a summary should also be provided in language intelligible to the lay reader. Researchers must avoid the use of jargon and technical language and should pitch the summary at the level of a science feature in a broadsheet newspaper. The summary may be used in FightMND publications; and
- **FightMND Research Symposium:** the Principal Investigator is required to present progress of the Clinical Trial study annually, and at the FightMND Research Symposium.
- **Notification of Milestone achievement:** 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 research site during the period of the Clinical Trial 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 Clinical Trial 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 Clinical Trial Grant (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 Clinical Trial 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 Clinical Trial 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 Clinical Trial 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 Director Dr Bec Sheean at bec.sheean@fightmnd.org.au, Research Co-ordinator Dr Davor Stanic at researchgrants@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 Clinical Trial 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 Clinical Trial grantees to acknowledge that their research has been supported wholly or in part by FightMND, either in the text or in a footnote. The Clinical Trial 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'sResearch 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/Sponsoring Institution must obtain the written consent of FightMND before taking any steps to exploit the results commercially. The Grantee and Administering/Sponsoring Institution accepts that FightMND may require a share of financial gain in return for its consent. This restriction shall continue to bind the parties notwithstanding any termination of the Clinical Trial Grant. For further detail, please see Appendix 1 - Intellectual property rights and commercial activities.

TERMS AND CONDITIONS

19. FIGHTMND MEETINGS AND EVENTS

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

19.2. There may be occasions where the granteeor other appropriate research team memberswill be asked to present their workrelating to the Clinical Trialat 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 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 Clinical Trial Grant must be repaid in full to FightMND forthwith.

22. INDEMNITY

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

APPENDIX 1

Intellectual Property rights and commercial activities

As a charity, FightMND is obliged to ensure that the outcomes of its funded research are applied for the public 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. TheAdministering 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 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.