



2023 FightMND Clinical Investigator Award

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Acronyms and Definitions

Administering Institution: Organisation responsible for administration of the research project, and the receipt and distribution of grant funds. A grant can only have one Administering Institution.

Applicant: Researcher leading the clinical research – the Primary Investigator (PI), who is responsible for the overall direction of the project, completion and lodgement of the application, and progress and reporting on the project.

The Applicant must obtain written commitment from their Head of Department (or equivalent) or Administering Institution, and must assume responsibility for undertaking and completing the activities outlined in the application. Where the project involves multi-site research, the Applicant must obtain written commitment from all Heads of Departments/Administering Institutions of collaborative partners not within the Administering Institution.

Career Disruption: A career disruption involves a prolonged interruption to an applicant's capacity to work, due to: Parental leave; Major illness/injury; or Carer responsibilities.

Collaboration and Collaborator/Collaborative Partner(s): All people, Investigators and Institutions involved in the research activity for the Clinical Investigator Award are considered to be collaborators. Collaboration may be between a combination of disciplines, Departments and/or Institutions and can include Institutions or individuals that provide specific resources that contribute to the research. Collaborators may be directly involved in the conduct of research activity but are not responsible for the direction and progress of the research. By encouraging collaborative agreements, FightMND is seeking that researchers consider looking beyond their discrete Departments, Institutions and disciplines, and to seek out people who may be doing similar research. This may allow for stronger and higher quality research proposals and reduce research duplication.

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

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

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

Within this scope, clinical research projects may include (but are not limited to):

- the preclinical development of new treatments and interventions for MND;
- testing the effectiveness of treatments for MND;
- validating specificity of biomarker(s) for MND; and
- imaging studies to advance capability of detecting MND, monitoring disease progression and/or testing efficacy of potential treatments in clinical trials.

Introduction

This document provides guidelines and information for the FightMND Clinical Investigator Award scheme in 2023. Applicants should familiarise themselves with all areas prior to commencing an application.

FightMND call for proposals:

FightMND are pleased to invite a call for Clinical Investigator Award applications from outstanding clinical researchers for novel, innovative clinical projects focused on defeating Motor Neurone Disease, and tackling one or more key issues contributing to the lack of effective treatments for MND.

APPLICATIONS OPEN:
03 November 2022

APPLICATIONS DUE:
23 March 2023 at 17:00 AEDT

RECIPIENTS NOTIFIED:
July 2023

Clinical Investigator Awards support 1-year projects up to the value of AUD \$100,000. Proposals for clinical research will be considered.

Support will not normally exceed one (1) year and applicants should submit proposals focused and compatible with this time frame. The continuation of funding within this period will be subject to periodic project review after the submission of satisfactory progress reports, which are required at six-monthly intervals.

Reporting is an important requirement of FightMND Fellowships (see Terms and Conditions 15). Please consider this when planning your research and experiments.

FightMND only supports work carried out in bona fide research institutions.



Research Objectives

Despite being first described over 150 years ago, MND remains a terminal diagnosis, and there is an urgent need for more effective treatments and a cure for the disease. The greatest weapons we have in the battle against MND are remarkable people and brilliant minds who are seeking to answer critical questions that will ultimately defeat MND.

Clinical Investigator Awards have been initiated by FightMND to inspire emerging clinical investigators with outstanding ability to focus on, tackle and resolve the vital questions needed to overcome MND, and to advance and encourage MND-focused clinical research in Australia.

Clinical Investigator Awards will build capacity and capabilities in the MND research sector by offering funding for a one (1) year clinical research project to emerging clinical investigators with outstanding ability who are seeking to focus on MND.

The purpose of the Clinical Investigator Award is to:

- support emerging clinical investigators to establish their research programs as they transition from their doctoral and post-doctoral training positions to their first clinical position in an academic environment; and
- enable medical graduates (or graduates of other clinical disciplines) with relevant experience and demonstrated expertise and ability, to apply for funding in their own name, build collaborations and further establish themselves as MND clinical researchers.

Applicants must demonstrate how their project outcomes will result in improved understanding, or accelerated translation of, potential therapeutics for MND and/or lead to more successful clinical trial outcomes for MND patients.

FightMND Clinical Investigator Awards seek to support research focused on fast-tracking potential therapeutics for MND through to clinical trial; and/or overcoming key challenges hindering the translation of promising discoveries into effective therapeutics, with the goal of improving the likelihood of positive clinical trial outcomes.



Eligibility Criteria

Eligibility

Applications are invited from research-based Institutions in Australia.

Eligible candidates and projects for this award must fulfill the following criteria:

- I. Applicants must be medical graduates (or graduates of other clinical disciplines) who have completed their clinical and research training (normally at a doctoral level);
- II. Applicants should be commencing or be in the early phase of their first clinical position (appointment of at least 5 years). Applicants should not have been in such a position for more than 3 years at the time applications are due;
- III. Applicants should be actively engaged in clinical research and have a clinical appointment of at least 0.2FTE in a university clinical department, teaching hospital or clinical research unit of a research institute (or equivalent);
- IV. Award funds are for research purposes and cannot be directed towards the applicant's salary;
- V. Clinical research projects must primarily be focused on MND;
- VI. Applicants are expected to present novel proposals deliverable in a 1-year time frame;
- VII. Proposals should be hypothesis-driven with defined aims and milestones;
- VIII. The clinical research plan **must** demonstrate how project outcomes will benefit people living with MND;

IX. Applicants must demonstrate outstanding research ability (relative to opportunity) with an established or developing track record of research impact and output in MND or related research. While MND experience is not essential, applicants are strongly encouraged to collaborate with those having more substantial expertise in MND clinical research;

X. Research proposals **must** be conducted in an Australian Institution. FightMND will not impose any criteria on the nationality of the applicant;

XI. A full detailed budget for the proposed project must be included. Note that FightMND does not fund Institutional indirect, overhead or oncosts. Salary oncosts are acceptable if itemised (e.g. superannuation, payroll tax, work cover);

XII. Capital equipment, depreciation, or maintenance of equipment will not be funded;

XIII. Applicants holding nationally competitive fellowships of 0.5FTE or higher are ineligible;

XIV. Applications must be made following the instructions in these guidelines and meet the eligibility criteria outlined in these guidelines.

All proposals should be supported by a reasonable body of preliminary data and demonstrate strong feasibility of delivery in the 1-year time frame. The funded project can commence on receipt of a signed Grant Agreement and first invoice and **must** commence within three (3) months of the agreed start date (or the grant shall lapse).

Application Procedure

Research proposals are submitted to FightMND and are independently peer-reviewed prior to consideration by FightMND's Grant Review Panel (GRP). The GRP's funding recommendations are then considered by the Board of FightMND. Key selection criteria in determining successful Clinical Investigator Awards will include the: i) track record and career achievements of the applicant; ii) quality and strength of the research project/plan; and iii) alignment of the project and applicant towards the core aims and mission of FightMND.

Submission of Applications

FightMND will only accept applications submitted via the Fluxx Grant Management System, which can be accessed at the following link <https://fightmnd.fluxx.io>.

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

- How to register a new user account in Fluxx (manual)
- How to submit a Clinical Investigator Award application in Fluxx (written manual)
- How to submit a Clinical Investigator Award application in Fluxx (guided video)

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

Requirements for Applications

Applications must include the following:

Application Form

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

- Primary Investigator.
- Name of the Institution where the project work will be undertaken.
- Collaborators.
- Administering institution information.
- Career Disruption (if applicable).
- **A lay summary of the project** suitable for media release if the application is successful (300 characters).
- **A lay summary** of the project suitable for publication on the FightMND website and newsletter if the application is successful (1500 characters).
- Provide background information necessary for readers without scientific or medical training to understand the rationale and feasibility of the proposed research project. It should also clearly describe the scientific objective the project is designed to achieve.
- Statement on the potential impact of the project (1250 characters).

Project Proposals

Proposals must be uploaded as a single pdf file onto Fluxx (max 5MB) and contain the following details:

Project Plan and Background

(max. 2 pages).

Include:

- Research Aims and Hypotheses;
- Background/Supporting Data;
- Research plan; and
- Description of the potential impact of the project for people living with MND.

References

(max. 10 references).

- Provide up to 10 references on a separate page immediately following the project plan and background.

Curriculum Vitae

(max. 3 pages).

- Provide a CV of the applicant.
- Include details on:
 - Career highlights and aspirations, awards and honours, community engagement;
 - Current position, detailing nature of clinical appointment;
 - Previous positions and training;
 - Full list of publications (separate to 3-page limit).

Declaration of Research Funding from Other Sources

Details of research funding obtained from other sources (actual or proposed) that relate to the Clinical Investigator Award's Hypothesis, Aims and Research Plan must be declared.

Include:

- Investigator, and Title of other Application;
- Funding Source/Organisation and Application ID;

- Role of Investigator on other Application;
- Total amount requested;
- Status – i.e. funded/under consideration.

Letter of Support from the Head of Department or Administering Institution

- Include a letter of support from the Head of Department or Administering Institution giving details of current appointment (including start date), and confirming that appropriate infrastructure, equipment, and consumables will be available and provided for the proposed project to completion.
- Where the project involves multi-site research, the Applicant must obtain written commitment from all Heads of Departments/Administering Institutions of collaborative partners not within the Administering Institution.

Statement on Collaboration Plan and Capabilities

(max. 1 page).

Where the viability of a project depends on collaboration/involvement with researchers, a statement on the specific role and contribution of the collaborator(s) and collaborative team should be prepared and added to the single pdf following the letter of support from the Head of Department or Administering Institution.

Include:

- Institution names and Departments where work will be carried out;
- Specific roles of each collaborator with evidence they are equipped to fulfil proposed role;
- Multi-organisational collaboration plan if applicable, including resolution of potential intellectual material and property issues and organisational barriers;

A confirmation letter (email) from each collaborator indicating their willingness to participate must be provided following the statement on collaboration plan and included as part of the single pdf to be submitted.

Referees

- Provide names and contact details of two academic referees. A letter of support from each is required. At least one of the referees should be independent.
- In their letter, referees should comment on:
 - Whether the applicant has the expertise to pursue the proposed research program;
 - How they see the applicants future in Australian clinical research;
 - The applicants position relative to peers – relative to opportunity;
 - Particular achievements of the applicant making them worthy of this award;
 - Their views on the quality of the research proposal.

Referees may choose to provide their letter of support in one of the following ways:

- 1) As part of this application. Referees will provide their letters of support to the applicant, who will attach the two letters to the pdf file; or
- 2) Directly to FightMND, by email to researchgrants@fightmnd.org.au.

The Letter of Support (LoS) from each referee must be received by the due date of the application. In the subject line of the email, please include the Applicant's Surname and the phrase 'Clinical Investigator Award LoS'.

The following components are to be uploaded on to the Fluxx application form separately to the Project Proposal:

Project Timeline

(max. 1 page).

- Include a detailed timeline for the project in Gantt chart format. Explanations relating to the timeline of the project, order of experiments and feasibility may be included.
- Note: An extension of the body of the 'Project Plan and Background' into the timeline page will make the application ineligible.

Reporting is an important requirement for FightMND grants (see Terms and Conditions 1.1 and 15). Please consider this when planning your experiments and project.

Budget

- Provide an itemised budget with breakdown of annual expenditure. This is entered into an excel spreadsheet template downloaded from the Fluxx application form (see page 7 of instruction manual, or instruction video at 4:05).

AND

- Provide a high-level budget summary of total expenditure per year, entered directly into Fluxx (see page 6 of instruction manual, or instruction video at 4:50).
- Budget items **can** include:
 - Salaries (salary for applicant will not be supported);
Salaries, where justified, will be supported up to a max. level of 50% of the Clinical Investigator Award;
 - Salary oncosts if itemised (e.g. superannuation, payroll tax, work cover);
 - Direct research costs (reagents, consumables, etc);
 - Travel for attendance and participation at academic conferences (max. \$5,000); and
 - Costs that enable open access for publications (but no other publication costs).
- Budget items **cannot** include:
 - Equipment;
 - Indirect, overhead or oncosts of the institution.

PhD Completion

- Provide evidence of the date that PhD was accepted.

Date and Term of Clinical Appointment

- Provide evidence of the term of clinical appointment, and date clinical appointment commenced.

How to Submit

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

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

The PROJECT PROPOSAL should include the following components:

- Project Plan and Background;
 - References;
 - Applicants Curriculum Vitae;
 - Declaration of research funding from other sources;
 - Letter of support from the Head of Department or Administering Institution;
 - Statement on Collaboration Plan and Capabilities (if applicable);
 - Name and Contact details of two Referees
 - Referee Letter's of Support (if submitting with the application).
- The TIMELINE, BUDGET, EVIDENCE of PhD ACCEPTANCE, and EVIDENCE of DATE and TERM of CLINICAL APPOINTMENT, should be uploaded separately into the Application form on the Fluxx Grant Management System.

Please note that applicants are limited to one (1) application for the Clinical Investigator Award scheme.

Application deadlines are described in this guideline.

Applications will NOT be accepted if submitted via email.



Reporting

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

REPORT	REPORTING FREQUENCY	DUE
Progress against pre-determined milestones and/or targets *	6-monthly	Every 6 months from receipt of funds
Final Report (including financial report and statement)	Once Only	At project completion, or within 12 weeks after 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	Biennially	During FightMND Research Symposium

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

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

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

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

Conflict of Interest – Reviewers and GRP

FightMND requires its independent reviewers and grant review panel to act in an ethical manner, declare 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.



Terms and Conditions

FightMND Grants

Terms and Conditions

All communication concerning FightMND Grant applications and administration should be addressed to the FightMND Cure Team, by email to researchgrants@fightmnd.org.au.

1. Funding Arrangements

1.1. FightMND research grants are time-limited and applicants should ensure that proper consideration is given to this in the proposal. When the project is approved in principle, the initial sum awarded by FightMND will be for the first six (6) months only. Approval of funding for subsequent invoices at six (6) monthly intervals will be subject to availability of funds and the receipt, from the grantee and/or Administering Institution, of satisfactory project progress and financial reports. Members of the FightMND team 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 FightMND at least eight weeks prior to the original completion date, by email to the FightMND Cure team at researchgrants@fightmnd.org.au.

1.3. The value of the FightMND Clinical Investigator Award is up to a total of \$100,000 AUD for project performance of one (1) year.

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

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

1.6. Payment of instalments is conditional on receipt and approval of satisfactory project progress and financial reports (see Terms and Conditions 1.1 and 15).

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. FightMND will not fund any equipment purchased as part of a FightMND grant.

3. Ethical Considerations

3.1. It is the responsibility of the Primary Investigator to 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 the Primary Investigator requires written agreement to continue the research under the direction of another qualified Investigator, ideally obtained prior to the absence. The grantee or an approved representative of the Administering Institution must apply to and notify FightMND by email to the FightMND Cure team 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 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 Institution against a claim for compensation or against any claims for which the Institution may be liable as an employer or otherwise.

6. Staff Management Responsibility

The Administering Institution must accept full responsibility for:

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

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

7. Termination of Employment

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

8. Employment Term Contracts

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

9. Maternity and Other Long-Term Leave

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

9.2. Maternity or parental leave is the responsibility of the Administering Institution employing staff undertaking a FightMND-funded project. Leave will be provided according to the Administering Institution's local terms and conditions of employment. The costs of such leave are the responsibility of the Administering Institution and are not provided for by FightMND.

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

10. Activation of an Awarded FightMND Grant

10.1. FightMND grants are activated on receipt of a signed Grant Agreement and receipt of the first invoice. If, for any reason, the start date of the project is delayed after the Grant Agreement has been returned, FightMND must be informed at once, a Grant Agreement Deed of Variation form completed, and a new start date agreed (see Terms and Conditions 11.2). If necessary, a revised Grant Agreement 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 and/or Administering Institution will have to reapply for funding in a future grant round, in competition with other applicants at the time.

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

11. Change of Terms of an Awarded FightMND Grant

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

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

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

12. Changes to Conditions of an Awarded FightMND Grant

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

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

13. Early Termination of an Awarded FightMND Grant

13.1. FightMND reserves the right to terminate the awarded 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. The Grant Primary Investigator or an approved representative of the Administering Institution must inform FightMND immediately when they are aware of a change of direction (see Terms and Conditions 11.2). There may, however, be circumstances in which the change is acceptable on scientific grounds;
- Failure to submit adequate progress reports, or serious and unresolvable problems identified by a site visit; and/or
- Work has ceased on the Grant, or the Primary Investigator has ceased to be actively involved in the project. FightMND must be informed immediately if this situation arises (see Terms and Conditions 11.2).

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

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

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

14. Extension to an Awarded FightMND Grant

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

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

15. Reports

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

- **Annual progress reports:** due every 12 months from the Grant start date, as stated on the executed Grant Agreement (see Terms and Conditions 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 three pages on project progress;
- **Final report:** required within twelve weeks after completion of the Grant project. A detailed final report covering the whole project will be substituted for the annual report. In addition, a summary should also be provided in language intelligible to the lay reader. Researchers must avoid the use of jargon and technical language and should pitch the summary at the level of a science feature in a broadsheet newspaper. The summary may be used in FightMND publications; and
- **FightMND Research Symposium:** the Primary Investigator is required to present progress of the project annually, and at the FightMND Research Symposium.

15.2. Instalments for the Grant will be paid only after receipt of progress reports and their approval by FightMND. Payment may be delayed 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 laboratories during the period of the Grant to discuss project progress, and welcomes invitations to do so.

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

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

17. Publications, Presentations, Acknowledgments and Publicity

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

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

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

17.4. Posters – costs and accessibility:

If FightMND-funded research is accepted for presentation as a poster, the costs of poster production may be claimed as part of the consumables budget (to a maximum of \$200 per grant). The poster must acknowledge FightMND as a source of funding and should include FightMND's logo. FightMND should be provided with an electronic copy of the poster for use on our website and social media.

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

17.6. Grantees and/or the Administering Institution must notify the FightMND Cure Research and Programs Director, Dr Bec Sheean, by email to bec.sheean@fightmnd.org.au, the FightMND Cure team at researchgrants@fightmnd.org.au, and the Marketing and Communications Director Anthea Hargreaves at anthea@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 grantee and/or author must acknowledge FightMND's support and display the FightMND logo where practical. All references to FightMND-funded work placed on websites, electronic bulletin boards and similar platforms must state clearly that the work is funded by "FightMND" and ideally a link should be included to the FightMND 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 grantees to acknowledge that their research has been supported wholly or in part by FightMND, either in the text or in a footnote. The Grant reference/ID must also be provided.

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

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

18. Patents, Copyright and Other Intellectual Property

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

19. FightMND Meetings and Events

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

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

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

20. FightMND Case Studies

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

21. Scientific Integrity

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

22. Indemnity

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



Appendix 1

Intellectual Property Rights and Commercial Activities

As a charity, FightMND is obliged to ensure that the outcomes of its funded research are applied for the public benefit. In some circumstances, this obligation may be best achieved through the protection of Intellectual Property resulting from the research and the facilitation of commercial exploitation of this Intellectual Property. The term 'Intellectual Property' (IP) describes any work or invention that results from original creative thought.

IP falls into different categories:

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

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

Therefore, for Grants where FightMND funding may lead to the generation of Intellectual Property, the following additional conditions shall apply:

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

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

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

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

1.4. The Administering Institution, Fellows, Grant holders, Laboratory Heads, co-Investigators and Sponsors 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 Fellows 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 FightMND has funded. Consent will not be unreasonably withheld, and FightMND will only refuse an Administering Institution's request where it considers that the proposed commercial exploitation would run counter to its interests and charitable objectives. In the event that FightMND does not provide a response to the Administering Institution's request within thirty (30) business days, the Institution or its technology transfer subsidiary will automatically have the right to proceed with such commercial exploitation. The Administering Institution is not required to seek FightMND's consent in assigning Intellectual Property to its technology transfer company.

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

I. All of the costs associated with commercialising of the Project IP (including patent and legal costs) will be paid by the Administering Institution. Out of any net proceeds received by the Administering Institution from commercialising the Project IP (after all of the Administering Institution's costs associated with commercialising the Project IP have 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 Grant funding provided under this agreement multiplied by five (5).

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

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

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