

2019

RESEARCH GRANTS

**FIGHT
MIND.**
IT TAKES PEOPLE

IMPACT
RESEARCH GRANTS

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ACRONYMS & DEFINITIONS

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

Applicant: Researcher who is leading the research - the Principal Investigator (PI). Responsible for the overall direction of the project. Responsible for completion and lodgment of the application, and responsible for progress and reporting on the project. The Applicant must obtain written commitment from their laboratory Head and Heads of Departments/Administering Institution and must assume responsibility for undertaking and completing the activities outlined in the application.

Biomarker: a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified.

Disease model: A disease model is an animal or cells displaying all or some of the pathological processes that are observed in the actual human or animal disease.

Gene therapy: the introduction of normal genes into cells in place of missing or defective ones in order to correct genetic disorders.

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

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

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

Within this scope, research projects may include:

- the pre-clinical development of new treatments and interventions for MND, or
- testing the effectiveness of treatments for MND.

INTRODUCTION

FightMND Call for Proposals: Grant applications for novel, innovative projects that tackle one or more key issues contributing to the lack of effective treatments for MND.

Applications Open: November 1st 2018

Application due: April 1st 2019

Recipients Announced: Late June 2019

FightMND is pleased to announce a call for IMPACT (IMProving and ACcelerating Translation) Grant applications to support projects focused on one or more of the following key issues contributing to the lack of translation of effective treatments through to clinical trial for MND.:

- I. Disease heterogeneity
- II. A lack of relevant preclinical models
- III. A lack of reliable disease biomarkers
- IV. The challenge of drug delivery into brain
- V. A lack of effective targeted gene therapies
- VI. The untapped potential of stem cell therapy

IMPACT Grants are for support of 2-year projects up to the value of \$250,000 AUD. Proposals for both discovery and translational stage proposals will be considered.

Such support will not normally exceed 2 years and applicants should submit proposals that are focused and compatible with a 2-year time frame. The continuation of a grant within this period will be subject to periodic review after the submission of satisfactory progress reports, which are required at six monthly intervals.

Reporting is an important requirement of awards (see award condition 15). Please consider this when planning your experiments and project.

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

RESEARCH OBJECTIVES

RESEARCH OBJECTIVES

Despite the first description of MND over 150 years ago, it remains a terminal diagnosis with no effective treatments or cure. There has been remarkable research progress in the last 25 years in genetic discoveries, development of animal models, and insights into disease mechanisms in MND, yet these findings have failed to translate into significant disease modifying therapies or a cure. Over 60 randomised controlled trials of proposed disease modifying drugs, largely based on animal studies, have failed to show positive results in MND (Mitsumoto et al. 2014) at an enormous cost to patients, their families, the healthcare system and drug companies.

The FightMND IMPACT Grants seek to support projects focused on overcoming one or more of the key challenges hindering the translation of promising discoveries into effective therapeutics with the goal of improving the likelihood of positive trial outcomes.

Priority areas for investigation are:

- I. Disease heterogeneity** – to more accurately define subgroups of MND patients to generate a precision medicine approach to improve recruitment into clinical trials.
- II. Disease models** – the development novel or improved animal and human models of MND, particularly sporadic MND, with the goal of improving the predictive power of preclinical models in discovering meaningful disease modifying therapies.
- III. Disease biomarkers** – the development and validation of sensitive and reliable candidate biomarkers for MND diagnosis, prognosis, disease progression and drug efficacy.
- IV. Drug delivery** – to improve Blood Brain Barrier permeability of new or existing drugs for the treatment of MND.
- V. Gene therapy** – to improve the targeting of treatments towards the underlying genetics of MND to address primary triggers and causes of the disease and reduce the ineffective targeting of downstream and secondary pathology.
- VI. Regenerative medicine** – the development or validation of stem cell transplantation techniques to explore the potential of stem cell therapy for MND.

GUIDELINES

GUIDELINES

IMPACT projects must demonstrate how developments in one of these key areas will result in improved or accelerated translation and lead to more successful clinical trial outcomes for MND patients.

The scope for these translational research grants is as outlined below:

- Where relevant, all disease model projects should utilise accepted models of MND and detail why these models are the most relevant for the proposal.
- **Disease Heterogeneity** – proposals can include, but are not limited to, assessment of patient clinical, genetic and molecular data to inspire tailored therapies.
- **Disease biomarker** – proposals should focus on further development of biomarkers previously identified in samples from well-characterised human subjects, supported by a reasonable body of preliminary data, Biomarkers should have a rational biological connection to the disease processes. Types of biomarkers can include:
 - **Companion Biomarkers** – Biomarkers that can assess target engagement and disease modification of specific clinical-stage therapeutics
 - **Neuroimaging** – Positron emission tomography (PET) ligands for target engagement and pharmacodynamic measurements of novel and repurposed therapeutics, and novel magnetic resonance imaging (MRI) methods to measure structural, blood flow, and white/grey matter changes in the brain
 - **CSF and blood-based biomarkers** – Multiplex ELISA and mass spectrometry of particular target(s) or transcriptomics, proteomics, metabolomics, and lipidomics signatures
 - **Functional activity measures** – Electroencephalogram (EEG), magnetoencephalography (MEG), transcranial magnetic stimulation (TMS), electromyography (EMG), electrical impedance myography (EIM).
 - **Other novel approaches** that are supported by compelling evidence
- **Disease models** – proposals should be focused on generating improved model systems that more accurately reflect human disease which will enhance the translation potential of therapeutics and lead to more successful clinical trial outcomes for MND patients. Priority disease model areas include:
 - **Novel disease models**
 - ▶ development and characterisation of new disease models
 - ▶ improvements to existing models
 - ▶ models that replicate one or more unique aspects of MND pathology previously undescribed in other model systems
 - ▶ confirmation and validation of newly discovered disease-causing genes

GUIDELINES

- **Sporadic MND or common pathology models:**
 - ▶ Models applicable to sporadic MND or relevant to a range of familial MND patients will be looked upon favourably
 - ▶ Models that mimic a range of MND pathologies, particularly those common to sporadic MND, e.g. oxidative stress, mislocalisation and aggregation of proteins, motor neuron loss, progressive paralysis and premature death due to MND phenotype.
- **Patient specific models:**
 - ▶ iPSC or induced neuronal models which display hallmark MND pathology
- **Other novel models supported by significant evidence**
- Researchers should clearly present the reasoning behind the type of model being developed, the benefits of the model over any existing disease models, and, where relevant, how evidence and validation of this new or improved model will be generated.
- **Drug Delivery** – proposals should improve the bioavailability of drugs by increasing blood-brain-barrier permeability or method of delivery. Proposals can include:
 - using novel mechanisms for drug delivery
 - establishing a high-throughput screening platform for brain-penetrating drugs to improve drug targeting and bioavailability.
- **Gene therapy** – proposals should improve the targeting of therapies against established and newly discovered MND genes. Proposals can include:
 - Improvements to existing gene therapy design or delivery
 - Novel gene therapy drugs or molecules
- **Regenerative medicine** – proposals should focus on advancing the potential of stem cell therapy for the treatment of MND by investigating:
 - the most suitable cell type for transplantation
 - the most effective source for generating these cells
 - the most effective route of delivery
 - the therapeutic mechanisms following transplantation
- Researchers should clearly present the impact of the proposal on translation and clinical trial outcomes for MND patients.

ELIGIBILITY CRITERIA

ELIGIBILITY

Applications are invited for research based in institutions in Australia.

Eligible candidates and projects for this award must fulfil the following criteria;

- I. Investigators at all academic levels are eligible to submit applications.
- II. Applicants are expected to present novel proposals that are deliverable in the 2-year time frame.
- III. Research proposals/projects targeting the treatment of sporadic MND will be considered favourably.
- IV. Proposals should be hypothesis-driven with defined aims and milestones.
- V. Within the scope of the project, the research plan **must** demonstrate how the project outcomes will improve the “bench-to-bedside” potential for promising therapeutics.
- VI. Applicants must demonstrate outstanding research ability 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 research and/or MND model systems where relevant.
- VII. Research proposals **must** be conducted in an Australian institution. At the time of application, the primary investigator may be based overseas. FightMND will not impose any criteria on the nationality of the applicant.
- VIII. Where possible the project demonstrates a collaborative approach.
- IX. A full detailed budget for the proposed project is to be included with year-to-year breakdown must be included.
- X. Capital equipment, depreciation, or maintenance of equipment will not be funded by FightMND grants without prior approval.
- XI. The contributions (if applicable) from other funding sources should also be included.

All proposals should be supported by a reasonable body of preliminary data and demonstrate strong feasibility of delivery in the 2-year time frame. The project funded can commence as soon as it is awarded and **must** commence within 3 months of the notification of the award (or the grant shall lapse).

APPLICATION PROCEDURE

APPLICATION PROCEDURE

Research proposals are submitted to FightMND and are independently peer reviewed prior to consideration by the Foundations' Scientific Advisory Panel (SAP). The SAP's funding recommendations are then considered by the Board of FightMND. Key factors in determination of awarding of these grants will include: i) the research track record of the applicants, ii) the quality and strength of the research project/plan, and iii) the alignment of the proposal with the core aims and mission of FightMND.

Proposals should include the following:

- **Completed Cover Sheet**
- **Lay Summary** (1/2 page max.) - for publication on the FightMND website and newsletter if the application is successful
 - ▶ Provide background information necessary for readers without scientific or medical training to understand the rationale and feasibility of the proposed research project. It should also clearly describe the scientific objective the project is designed to achieve.
- **Name of the institution where the project work will be undertaken**
 - ▶ Including a letter of support from the institution confirming that appropriate infrastructure, equipment, and consumables will be available and provided for the proposed project to completion.
- **Project Plan, Background, and Timeline** (maximum 5 pages). Include:
 - ▶ Research Aims and hypotheses
 - ▶ Background/Supporting Data
 - ▶ Research plan
 - ▶ Budget justification including a year-by-year breakdown
 - ▶ Description of the potential impact of the project
 - ▶ References (max.2 pages, does not count towards 5 pages)
- **Curriculum Vitae** of each CI (max.2 pages per CI, including details on career disruption where relevant)

Please note that applicants are limited to one (1) CIA and two (2) Co-CI applications for this grant scheme.

The application deadlines are described in this guideline. Minimum size font for applications is size 12 and margins are 1 cm. Applications are to be submitted as a single PDF document and forwarded to Dr Bec Sheean, FightMND Research Manager at research@fightmnd.org.au before the closing date for applications.

PRIVACY, CONFLICT OF INTEREST

PRIVACY AND CONFIDENTIALITY

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

Applicants consent to the information supplied as part of their application being disclosed for the purposes of the evaluation and administration of the grant. Such disclosure includes but is not limited to members of the Scientific Advisory Panel (SAP), independent readers/assessors requested by the SAP to provide advice on the applications, the FightMND Board and relevant employees of FightMND involved in the research grant process.

Applicants acknowledge that announcement of the funded grants will involve a dissemination of information to the public about the general nature of the funded grants.

CONFLICT OF INTEREST SAP MEMBERS

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

ACKNOWLEDGEMENT OF SUPPORT

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

TERMS & CONDITIONS

FIGHTMND IMPACT GRANTS

TERMS & CONDITIONS

All communication concerning applications and administration should be addressed to Dr Bec Sheean, Research Manager, FightMND, research@fightmnd.org.au

1 FUNDING ARRANGEMENTS

1.1 FightMND IMPACT 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 the receipt, from the grantee, of a satisfactory project progress and financial reports. Members of the Foundation, SAP and Board will review progress reports to decide outcomes.

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

1.3 The value of the award is up to \$250,000 total for project performance of 2 years.

1.4 FightMND will not meet indirect, overhead or on-costs of the institution such as: general travel, finance services, staff facilities, staff development, public relations, publication costs, institutional libraries, routine secretarial work, personnel services, stationery or contributions to general departmental costs.

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

1.6 Payment of installments is conditional on receipt and approval of satisfactory project progress and financial reports (see condition 1.1 and 15.1)

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

TERMS & CONDITIONS

2 EQUIPMENT

2.1 In general, FightMND will not fund any equipment purchase as part of this award. However, following written approval from FightMND, equipment purchased with FightMND funds within the terms of the award must not be modified or removed from the grantee's institution without FightMND's permission. Should the Primary Investigator move to another institution during the tenure of the award, FightMND reserves the right that the equipment be transferred with him/her following negotiation.

3 ETHICAL CONSIDERATIONS

3.1 It is the responsibility of the Primary Investigator to make due application for ethical committee approval that may be required 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 the Head of Department must apply to and notify the FightMND Research Manager Dr Bec Sheean at research@fightmnd.org.au with an explanation of the situation, providing details of the arrangements for conducting the research during their absence (see grant condition 11.2).

5 RECRUITMENT AND EMPLOYMENT OF STAFF

5.1 FightMND does not act as employer and, therefore, in all cases where financial support is provided for the employment of staff, the host institution undertakes to issue a contract of employment in accordance with any other relevant Act relating to the conditions of employment.

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

TERMS & CONDITIONS

6 STAFF MANAGEMENT RESPONSIBILITY

The host institution must accept full responsibility for:

6.1 The management, monitoring and control for all those staff (permanent, temporary and students) employed or involved in any research funded as a result of a FightMND award;

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 award supported project continues beyond the period of the award, the host institution will be solely responsible for all costs beyond the period of the award. FightMND accepts no liability for contracts and costs extending beyond the defined grant period.

8 EMPLOYMENT TERM CONTRACTS

8.1 Where members of staff have been under contract to the host institution prior to the activation of the FightMND award, FightMND will not reimburse costs attributed to any prior commitment. This includes any redundancy payments due for service prior to the grant period.

8.2 The contract of employment offered must not extend beyond the termination of the grant (unless the host institution wishes to extend the contract at its own expense).

9 MATERNITY AND OTHER LONG-TERM LEAVE

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

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

9.3 If a FightMND funded employee is due to take any planned long-term leave, the award holder should inform FightMND of the dates in advance. This will enable discussion to decide whether the award should be suspended for the period of absence until full time employment can be resumed (see grant conditions 4 and 11.2). If unplanned long-term leave occurs, the award holder or the Head of Department should contact FightMND as soon as possible to discuss the situation with the Research Manager.

TERMS & CONDITIONS

10 ACTIVATION OF AWARD

10.1 Awards are activated on receipt of a signed grant agreement and receipt of the first invoice. If, for any reason, the start date of the project is delayed after the form has been returned, FightMND must be informed at once, a *Grant Amendment Application* completed, and a new start date agreed (see grant condition 11.2). If necessary, a revised Grant Agreement form will need to be completed and returned.

10.2 If the project does not start within three (3) months of the original agreed start date, FightMND may withdraw the award offer. The grantee will have to reapply for funding in a future awards round, in competition with other applicants at the time.

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

11 CHANGE OF TERMS OF AWARD

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

11.2 Grantees will be required to complete an *Award Amendment Application* detailing any and all proposed changes to the project. Applications must be submitted (where possible) at least eight weeks prior to the changes taking place and submitted for approval to FightMND Research Manager Dr Bec Sheean at research@fightmnd.org.au. FightMND must be kept informed at all time of any changes to the original grant.

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

12 CHANGES TO CONDITIONS OF AWARD

12.1 FightMND reserves the right to change the Terms and Conditions of IMPACT Grant Awards at any time. If this occurs during the lifetime of an award, the revised Terms and Conditions may be applied in place of those issued at the time of the original award.

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

TERMS & CONDITIONS

13 EARLY TERMINATION OF AN AWARD

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

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

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

13.2 If an award is terminated, FightMND will meet costs properly and necessarily incurred under the award 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 termination of the award.

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

14 EXTENSION TO AWARDS

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

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

TERMS & CONDITIONS

15 REPORTS

15.1 The Investigator is required to submit the following reports:

- **Annual progress reports:** due every 12 months from the start date, as stated on the executed agreement (see grant condition 1.1). A short summary in language intelligible to the lay reader should also be submitted for possible use in FightMND publications and on our website.
- **Interim reports:** the Principal Investigator will be required to provide brief six monthly reports of no more than two pages on project progress.
- **Final report:** is required within six weeks of the end of the 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.
- **FightMND Research Symposium:** the Principal Investigator is required to present progress of the award project annually at the FightMND Research Symposium.

15.2 The final installment of the award will be only paid after receipt of the final report and its approval by FightMND. Payment may be delayed further if reports are not submitted on time and/or if clarification is required.

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

16 SITE VISITS AND PROGRESS MEETINGS

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

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

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

TERMS & CONDITIONS

17 PUBLICATIONS, PRESENTATIONS, ACKNOWLEDGMENTS AND PUBLICITY

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

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

17.3 **Open Access Policy:** Grantees of awards from FightMND are mandated to make their peer reviewed papers, directly arising from the grant, available through open access. These research papers should be available within the PubMed Central repository as soon as possible, but definitely within six months of publication of the paper. Publication costs can be included in the project budget.

17.4 **Posters: costs and accessibility:** If FightMND funded research is accepted for presentation as a poster, the costs of poster production may be claimed as part of the consumables budget (to a maximum of \$250 per project grant). The poster must acknowledge FightMND as a source of funding and should include FightMND's logo. FightMND should be provided with an electronic copy of the poster for use on our website and social media.

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

17.6 Grantees and the host institution must notify FightMND's Research Manager Dr Bec Sheean at research@fightmnd.org.au and Communications Manager Andrew Holmes at andrew@fightmnd.org.au at least five working days in advance of any publicity arising from research wholly or co-funded by a FightMND grant. Any press release or other material including reference to FightMND funded research must be approved by our team before it is released to the media.

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

17.8 Grantees must ensure that the FightMND's support is acknowledged in all publications, presentations and similar. 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 must also be provided.

TERMS & CONDITIONS

17.9 When speaking publicly and to representatives of the media about FightMND-funded research, grantees and researchers should ensure they make it clear to the media and others that they should be presented as a “FightMND-funded scientist”. Please note that researchers should consult our Research Manager Dr Bec Sheean and Communications Manager Andrew Holmes at research@fightmnd.org.au and andrew@fightmnd.org.au, respectively, before speaking to the media.

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

18 PATENTS, COPYRIGHT AND OTHER INTELLECTUAL PROPERTY

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

19 FIGHTMND MEETINGS AND EVENTS

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

19.2 There may be occasions where the grantee will be asked to present their work at scientific and or health care professionals’ meetings.

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

20 FIGHTMND CASE STUDIES

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

21 SCIENTIFIC INTEGRITY

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

TERMS & CONDITIONS

22 INDEMNITY

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

APPENDIX 1

Intellectual Property rights and commercial activities.

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

The term intellectual property (IP) describes any work or invention that results from original creative thought.

IP falls into different categories:

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

Some of these protections need to be registered (trademarks, patents) and some do not (copyright, design rights). If the IP is not protected, another individual or 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 grant awards under this agreement (Project IP) shall be owned by the Administering Institution.

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

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

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

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

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

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

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

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

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- 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