

# SUBMISSION GUIDELINES

## LETTER OF INTENT

Please use the template below as an example of the format required in submission of your letter of intent. Letter of intent submissions should be submitted with a minimum size 12 font, 1 cm margins and must not exceed 3 pages.

Principal Investigator:	Institution:
Biostatistician:	Institution:
Pharmacologist (if applicable):	Institution:
Estimated direct costs for the first year of funding:	

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

Primary Study aims:		
Secondary aims (if any):		
Briefly describe any relevant pre-clinical or clinical evidence that supports the study rationale:		
Briefly describe the study design:		
Indicate how the primary aims of this preliminary study will help optimise the design of the eventual definitive phase III trial:		
Number of subjects to be enrolled: ~		
Number of Australian Clinical Sites :		
Describe how the intervention will be administered, including dose and duration as applicable. Do you have drug and placebo in hand for the study?		
Does this preliminary study include placebo or control groups? If "yes" provide applicable rationale	YES	NO
Does the trial drug have preclinical efficacy data in at least 2 MND disease models - one of which MUST be a representative model of sporadic disease	YES	NO

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Describe the plan for sample collections and willingness to share samples with the MND research community:

Describe the pharmacodynamic markers that will be used in the trial:

Describe ethical and consent considerations of the proposed protocol:

Participating pharmaceutical or device manufacturing company (if any):

Do you hold or have you applied for an IND/IDE for this protocol?  
(Please note: it is NOT a requirement for trials in Australia)

YES

NO

List all cores that you are interested in utilising from a FightMND approved contract research organisation (CRO) - see "Research Objective" page 4 for details