



**Australian Government**  
**Department of Health**

# **Commonwealth Standard Grant Agreement**

between the Commonwealth represented by

**Department of Health**

and

**National Stroke Foundation**

Commonwealth Standard Grant Agreement

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## Grant Agreement [MRFF-N-SF]

Once completed, this document, together with each set of Grant Details and the Commonwealth Standard Grant Conditions (Schedule 1), forms an Agreement between the Commonwealth and the Grantee.

### Parties to this Agreement

#### The Grantee

Full legal name of Grantee	National Stroke Foundation
Legal entity type (e.g. individual, incorporated association, company, partnership, etc)	Australian Public Company, Limited by Guarantee
Trading or business name	Stroke Foundation
Any relevant licence, registration or provider number	N/A
Australian Business Number (ABN) or other entity identifiers	42 006 173 379
Australian Company Number (ACN)	006 173 379
Registered for Goods and Services Tax (GST)?	Yes
Date from which GST registration was effective?	1 July 2000
Registered office (physical/postal)	Physical and postal: Level 7, 461 Bourke Street MELBOURNE VIC 3000
Relevant business place (if different)	N/A
Telephone	03 9918 7225
Email	S 22 <a href="mailto:@strokefoundation.org.au">@strokefoundation.org.au</a>

#### The Commonwealth

The Commonwealth of Australia represented by the  
Department of Health  
of Sirius Building, Furzer Street, Woden Town Centre, ACT 2606  
ABN 83 605 426 759

The Department of Industry, Innovation and Science will manage the Agreement on behalf of the Department of Health.

## Background

The Commonwealth has agreed to enter this Agreement under which the Commonwealth will provide the Grantee with one or more Grants for the purpose of assisting the Grantee to undertake the associated Activity.

The Grantee agrees to use the Grant and undertake the Activity in accordance with this Agreement and the relevant Grant Details.

## Scope of this Agreement

This Agreement comprises:

- (a) this document;
- (b) the Supplementary Terms (if any);
- (c) the Standard Grant Conditions (Schedule 1);
- (d) the Grant Details;
- (e) any other document referenced or incorporated in the Grant Details.

If there is any ambiguity or inconsistency between the documents comprising this Agreement in relation to a Grant, the document appearing higher in the list will have precedence to the extent of the ambiguity or inconsistency.

This Agreement represents the Parties' entire agreement in relation to each Grant provided under it and the relevant Activity and supersedes all prior representations, communications, agreements, statements and understandings, whether oral or in writing.

Certain information contained in or provided under this Agreement may be used for public reporting purposes.

## Grant Details [MRFF-N-SF]

### A. Purpose of the Grant

This Grant is being provided as part of the Accelerated Research Program – neurological (National Stroke Foundation) research grant opportunity.

The expected outcomes of the Grant Activity are to accelerate stroke research or develop new diagnoses, treatments and cures.

The Accelerated Research Program forms part of the \$20 billion Medical Research Future Fund, established to provide a sustainable source of funding for vital medical research over the medium to longer term.

The objectives of the program are to support research in emerging health priority areas and areas of unmet need, such as rare cancers, and rare diseases and illnesses.

### B. Activity

The Activity is made up of your Project and all eligible project activities as specified in these Grant Details.

#### Project Title

This Agreement covers two distinct elements:

1. Australian Living Guidelines for Stroke Management
2. “Return to life, return to work”. A targeted clinical research investment in stroke recovery for young survivors.

#### Project Outcomes

##### ***Australian Living Guidelines for Stroke Management***

The project will develop the Living Clinical Guidelines for Stroke Management, a digital platform, accessible to clinicians on tablet, phone and desktop. The online publication method will enable the guidelines to be updated in real time. The project will design, build and test enhancements to the current online tools and methods to improve efficiency and transparency of innovative ‘evidence surveillance’ systems.

Description: The Living Clinical Guidelines for Stroke Management will draw on latest technologies and new ways of working to develop efficient ‘evidence surveillance’ systems. These systems will continually identify new research, incorporate this research into living systematic reviews and rapidly update individual guideline recommendations whenever there is an important change in the evidence.

- The Living Clinical guidelines for Stroke Management project will develop and evaluate an Australian first system, requiring development of several interlinking components:
- An infrastructure platform enabling access to a suite of technological tools;
- Valid, reliable transparent methods producing living guidelines;

- A production model for living guidelines addressing governance mechanisms, workflows, training requirements, incentives for participation and working with government to ensure new approaches;
- International collaboration with groups producing systematic reviews and guidelines;
- Innovative stakeholder engagement approach including new approaches to guideline co-production and effective, continual public consultation and dissemination.

Expected outcome: The project will demonstrate improvement in stroke care by developing a model of producing trustworthy, contemporary clinical guidelines.

***“Return to life, return to work”. A targeted clinical research investment in stroke recovery for young survivors.***

This project will facilitate clinical research activity and promote greater access to innovative and cutting edge treatments for stroke survivors of working age.

Description: The 'Return to life, return to work' package will focus on clinical trials of recovery and rehabilitation interventions for stroke survivors.

- Call for clinical research applications that address the topic of 'Return to work, return to life' including proposals for trialling Perispinal Etanercept in chronic stroke;
- Endorsement of trial to be sought from the Australasian Stroke Trials Network;
- Training of staff at trial sites, including certification for Good Clinical Practice;
- Establishment of a Data Safety Committee and finalisation of Charter;
- Publication of study protocol in an international scientific journal;
- Targeted number of patients to be recruited to the study;
- Clinical trial close out, closure of sites, results written up and presented and a publication plan.

Expected outcome: The 'Return to life, return to work' research package will support research in young stroke recovery, an emerging priority area of unmet need which has the potential to provide new treatments to those suffering from the impact of stroke. It is expected this will result in healthier Australians with a measurable impact on the health system's sustainability, productivity and health outcomes.

In undertaking the Activity, the Grantee must comply with the requirements of the Grant Opportunity Guidelines (as in force from time-to-time).

You must notify us about events relating to the Project and provide an opportunity for the Minister or their representative to attend.

### **C. Duration of the Grant**

The Activity starts on the date this contract is executed and ends on 30 June 2021, the Completion Date.

## Activity Schedule - Australian Living Guidelines for Stroke Management

No.	Title and description	Due date
1	Project start date	30 July 2018
2	Project Evaluation – create evaluation plan	30 September 2018
3	Establish platform and methods – design and build	31 December 2018
4	Create and maintain living guidelines – initial update	1 April 2019
5	Engage the stroke community, including the public, health professionals and guideline development groups – initial mechanisms established	1 April 2019
6	Establish platform and methods – test and refine	31 December 2019
7	Create and maintain living guidelines – ongoing until project end	30 June 2021
8	Engage the stroke community, including the public, health professionals and guideline development groups – ongoing until project end	30 June 2021
9	Project end date	30 June 2021

## Activity Schedule - "Return to life, return to work".

No.	Title and description	Due date
1	Project start date.	30 July 2018
2	Call for research applications concludes.	31 December 2018
3	Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration.	30 June 2019
4	Training of staff at trial sites concludes.	31 December 2019
5	Publication of study protocol and statistical analysis plan.	31 December 2020

No.	Title and description	Due date
6	Patient recruitment concludes.	31 December 2020
7	Establishment of Data Safety and Monitoring Committee and its Charter is finalised.	30 June 2021
8	Clinical Trial close out, closure of sites, results written up and presented, publication plan	30 June 2021
9	Project end date	30 June 2021

#### D. Payment of the Grant

The total amount of the Grant is \$2,500,000 (plus GST if applicable).

The Grant will be provided at up to 100 per cent of eligible expenditure as defined in the Grant Opportunity Guidelines subject to satisfactory progress towards milestones and availability of Program funds.

The Grant will be paid in accordance with clause ST2.

The Grant will be paid according to the following schedule. Payments are subject to satisfactory progress on the Project and compliance by the Grantee with its obligations under this Agreement.

S 47G

Payment event	Payment amount (GST excl)	Payment date
		July 2018
		February 2019
		February 2020
		February 2021
		June 2021
Total	\$2,500,000	

#### Invoicing

The Grantee agrees to allow the Commonwealth to issue it with a Recipient Created Tax Invoice (RCTI) for any taxable supplies it makes in relation to the Activity.

#### E. Reporting

The Grantee agrees to provide the following reports to the Commonwealth representative in accordance with the Reporting Templates (Schedule 2).

Report type	Period start date	Period end date	Agreed evidence	Due date
Progress	Project Start Date	31 December 2018	Satisfactory completion of the progress report template	31 January 2019
Progress	1 January 2019	31 December 2019	Satisfactory completion of the progress report template	31 January 2020
Progress	1 January 2020	31 December 2020	Satisfactory completion of the progress report template	31 January 2021
End of Project	Project Start Date	30 June 2021	Satisfactory completion of the final report template	28 September 2021
Independent audit report	Project Start Date	30 June 2021	Satisfactory report completed by independent auditor	28 September 2021

During the Agreement period, we may ask you for ad-hoc reports on your project. You must provide these reports in the timeframes notified by the Commonwealth.

## F. Party representatives and address for notices

### Grantee's representative and address

Grantee's representative name	S 22
Position	Chief Executive Officer
Postal/physical address(es)	Level 7, 461 Bourke Street MELBOURNE VIC 3000
Business hours telephone	S 22
Mobile	S 22
E-mail	S 22 <a href="mailto:____@strokefoundation.org.au">____@strokefoundation.org.au</a>

### Commonwealth representative and address

Name of representative	S 22
Position	Program Manager
Postal/physical address(es)	Postal: GPO Box 2013, Canberra ACT 2601 Physical: Level 5, 111 Bourke Street, Melbourne VIC 3000
Business hours telephone	S 22
E-mail	<a href="mailto:arp@industry.gov.au">arp@industry.gov.au</a>

The Parties' representatives will be responsible for liaison and the day-to-day management of the Grant, as well as accepting and issuing any written notices in relation to the Grant.

## G. Activity Material

Not applicable.

## Supplementary Terms

### ST1. Other contributions

Not applicable

### ST2. Activity budget

ST2.1 The Grantee agrees to use the Grant and undertake the Activity consistently with the activity budget in the following table:

Eligible expenditure item	Estimated expenditure 2018-19	Estimated expenditure 2019-20	Estimated expenditure 2020-21	Total
Plant and equipment	<b>S 47G</b>			
Purchase of materials				
Labour				
Contract expenditure				
Travel Costs				
Other eligible expenditure				
Total Project costs				

Figures in the above table are GST inclusive amounts less GST credits that can be claimed in relation to the expenditure.

ST2.2 Subject to sufficient appropriation being available, the Grant will be paid up to the Annual Capped Amounts over the financial years specified in the following table.

#### Annual Capped Amounts

Financial year	Annual capped amount (GST excl)
2017-18	<b>S 47G</b>
2018-19	
2019-20	
2020-21	
<b>Total</b>	<b>\$2,500,000</b>

ST2.3 The Commonwealth is not required to make a payment if it would result in the amount paid in a financial year exceeding the Annual Capped Amount for that financial year specified in the table under clause ST2.2.

ST2.4 In accordance with the activity budget under clause ST2.1, the Annual Capped Amounts may not be exceeded unless the Commonwealth specifically approves an increase of that amount under clause ST2.7.

ST2.5 Subject to this clause, the Grantee may reallocate expenditure in respect of categories of expenditure in the activity budget, provided it does not materially change the Activity, any

Milestone(s) set out in this Agreement, or cause the Grantee to be in breach of any of its obligations under this Agreement.

ST2.6 The Grantee must give the Commonwealth:

- (a) at any time the Grantee wishes to request a variation to any one or more of the Annual Capped Amounts; or
- (b) if otherwise requested by the Commonwealth,

a revised activity budget in a form acceptable to the Commonwealth. The revised Activity Budget must clearly identify any proposed changes, including of any proposed changes to the Annual Capped Amounts, and explain the reasons for the proposed changes.

ST2.7 The Commonwealth may, at its discretion, approve or reject a revised activity budget provided under clause ST2.6 and/or any proposed changes to the Annual Capped Amounts. The Commonwealth's approval may be granted subject to conditions.

ST2.8 If a revised activity budget and any proposed changes to the Annual Capped Amounts are approved by the Commonwealth, then it will become the activity budget and, if relevant, the Annual Capped Amounts will be adjusted accordingly.

### ST3. Intellectual property in Activity Material

Not applicable

### ST4. Access/monitoring/inspection

ST4.1 The Grantee agrees to give the Commonwealth, or any persons authorised in writing by the Commonwealth:

- (a) access to premises where the Activity is being performed and/or where Material relating to the Activity is kept within the time period specified in a Commonwealth notice; and
- (b) permission to inspect and take copies of any Material relevant to the Activity.

ST4.2 The Auditor-General and any information officer under the *Australian Information Commissioner Act 2010* (Cth) (including their delegates) are persons authorised for the purposes of clause ST4.1.

ST4.3 This clause ST4 does not detract from the statutory powers of the Auditor-General or an Information Officer (including their delegates).

### ST5. Equipment and assets

Not applicable

### ST6. Specified personnel

Not applicable.

### ST7. Relevant qualifications, checks, licences or skills

Not applicable

### ST8. Commonwealth material

Not applicable

## ST9. Jurisdiction

ST9.1 This Agreement is governed by the law of the Australian Capital Territory.

## ST10. Grantee trustee of trust (if applicable)

ST10.1 In this Agreement, Trust means the trust specified in the Parties to the Agreement section of this Agreement.

ST10.2 The Grantee warrants that:

- (a) it is the sole trustee of the Trust; and
- (b) it has full and valid power and authority to enter into this Agreement and perform the obligations under it on behalf of the Trust; and
- (c) it has entered into this Agreement for the proper administration of the Trust; and
- (d) all necessary resolutions, consents, approvals and procedures have been obtained or duly satisfied to enter into this Agreement and perform the obligations under it; and
- (e) it has the right to be indemnified out of the assets of the Trust for all liabilities incurred by it under this Agreement.

## ST11. Fraud

ST11.1 In this Agreement, Fraud means dishonestly obtaining a benefit, or causing a loss, by deception or other means, and includes alleged, attempted, suspected or detected fraud.

ST11.2 The Grantee must ensure its personnel and subcontractors do not engage in any Fraud in relation to the Activity.

ST11.3 If the Grantee becomes aware of:

- (a) any Fraud in relation to the performance of the Activity; or
- (b) any other Fraud that has had or may have an effect on the performance of the Activity;

then it must within 5 business days report the matter to the Commonwealth and all appropriate law enforcement and regulatory agencies.

ST11.4 The Grantee must, at its own cost, investigate any Fraud referred to in clause ST11.3 in accordance with the Australian Government Investigations Standards available at [www.ag.gov.au](http://www.ag.gov.au).

ST11.5 The Commonwealth may, at its discretion, investigate any Fraud in relation to the Activity. The Grantee agrees to co-operate and provide all reasonable assistance at its own cost with any such investigation.

ST11.6 This clause survives the termination or expiry of the Agreement.

## ST12. Step-in rights

Not applicable

## ST13. Grant administrator

Not applicable

## ST14. Management Adviser

Not applicable

## ST15. Indemnities

ST15.1 The Grantee indemnifies the Commonwealth, its officers, employees and contractors against any claim, loss or damage arising in connection with the Activity.

ST15.2 The Grantee's obligation to indemnify the Commonwealth will reduce proportionally to the extent any act or omission involving fault on the part of the Commonwealth contributed to the claim, loss or damage.

## ST16. Compliance with legislation

ST16.1 In this Agreement:

**Legislation** means a provision of a statute or subordinate legislation of the Commonwealth, or of a State, Territory or local authority

ST16.2 The Grantee agrees to comply with all Legislation applicable to its performance of this Agreement.

ST16.3 The Grantee agrees, in carrying out its obligations under this Agreement, to comply with any of the Commonwealth's policies as notified, referred or made available by the Commonwealth to the Grantee (including by reference to an internet site).

ST16.4 In carrying out the Activity, the Grantee must comply with the following applicable policies/laws:

- (a) NHMRC/ARC/UA Australian Code for the Responsible Conduct of Research (2007)
- (b) NHMRC/ARC/UA National Statement on Ethical Conduct in Human Research (2007, updated 2014)

## ST17. Work health and safety

ST17.1 The Grantee agrees to ensure that it complies at all times with all applicable work health and safety legislative and regulatory requirements and any additional work health and safety requirements set out in the Grant Details.

ST17.2 If requested by the Commonwealth, the Grantee agrees to provide copies of its work health and safety management plans and processes and such other details of the arrangements it has in place to meet the requirements referred to in clause ST17.1.

ST17.3 When using the Commonwealth's premises or facilities, the Grantee agrees to comply with all reasonable directions and procedures relating to work health and safety and security in effect at those premises or in regard to those facilities, as notified by the Commonwealth or as might reasonably be inferred from the use to which the premises or facilities are being put.

## ST18. Transition

Not applicable

## ST19. Corporate Governance

ST19.1 The Grantee warrants that nothing in its constitution conflicts with its obligations under this Agreement.

ST19.2 The Grantee agrees to provide a copy of its constitution to the Commonwealth upon request and inform the Commonwealth whenever there is a change in the Grantee's constitution, structure or management.

## ST20. Counterparts

ST20.1 This Agreement may be executed in any number of counterparts. All counterparts, taken together, constitute one instrument. A Party may execute this Agreement by signing any counterpart.

## Schedule 1: Commonwealth Standard Grant Conditions

### 1. Undertaking the Activity

1.1 The Grantee agrees to undertake the Activity for the purpose of the Grant in accordance with this Agreement.

1.2 The Grantee is fully responsible for the Activity and for ensuring the performance of all its obligations under this Agreement in accordance with all relevant laws. The Grantee will not be relieved of that responsibility because of:

- (a) the grant or withholding of any approval or the exercise or non-exercise of any right by the Commonwealth; or
- (b) any payment to, or withholding of any payment from, the Grantee under this Agreement.

### 2. Payment of the Grant

2.1 The Commonwealth agrees to pay the Grant to the Grantee in accordance with the Grant Details.

2.2 Notwithstanding any other provision of this Agreement, the Commonwealth may by notice withhold payment of any amount of the Grant and/or take any other action specified in the Supplementary Terms if it reasonably believes that:

- (a) the Grantee has not complied with this Agreement
- (b) the Grantee is unlikely to be able to perform the Activity or manage the Grant in accordance with this Agreement; or
- (c) there is a serious concern relating to this Agreement that requires investigation.

2.3 A notice under clause 2.2 will contain the reasons any action taken under clause 2.2 and, where relevant, the steps the Grantee can take to address those reasons.

2.4 The Commonwealth will only be obliged to pay the withheld amount once the Grantee has addressed the reasons contained in a notice under clause 2.2 to the Commonwealth's reasonable satisfaction.

### 3. Acknowledgements

3.1 The Grantee agrees not to make any public announcement, including by social media, in connection with the awarding of the Grant without the Commonwealth's prior written approval.

3.2 The Grantee agrees to acknowledge the Commonwealth's support in all Material, publications and promotional and advertising materials published in connection with this Agreement. The Commonwealth may notify the Grantee of the form of acknowledgement that the Grantee is to use.

### 4. Notices

4.1 Each Party agrees to promptly notify the other Party of anything reasonably likely to adversely affect the undertaking of the Activity, management of the Grant or its performance of any of its other requirements under this Agreement.

4.2 A notice given by a Party under this Agreement must be in writing and addressed to the other Party's representative as set out in the Grant Details or as most recently updated by notice

given in accordance with this clause.

## 5. Relationship between the Parties

5.1 A Party is not by virtue of this Agreement the employee, agent or partner of the other Party and is not authorised to bind or represent the other Party.

## 6. Subcontracting

6.1 The Grantee is responsible for the performance of its obligations under this Agreement, including in relation to any tasks undertaken by subcontractors.

6.2 The Grantee agrees to make available to the Commonwealth the details of any of its subcontractors engaged to perform any tasks in relation to this Agreement upon request.

## 7. Conflict of interest

7.1 Other than those which have already been disclosed to the Commonwealth, the Grantee warrants that, to the best of its knowledge, at the date of this Agreement, neither it nor its officers have any actual, perceived or potential conflicts of interest in relation the Activity.

7.2 If during the term of the Agreement, any actual, perceived or potential conflict arises or there is any material change to a previously disclosed conflict of interest, the Grantee agrees to:

- (a) notify the Commonwealth promptly and make full disclosure of all relevant information relating to the conflict; and
- (b) take any steps the Commonwealth reasonably requires to resolve or otherwise deal with that conflict.

## 8. Variation, assignment and waiver

8.1 This Agreement may be varied in writing only, signed by both Parties.

8.2 The Grantee cannot assign its obligations, and agrees not to assign its rights, under this Agreement without the Commonwealth's prior approval.

8.3 The Grantee agrees not to enter into negotiations with any other person for the purposes of entering into an arrangement that will require novation of, or involve any assignment of rights under, this Agreement without first consulting the Commonwealth.

8.4 A waiver by a Party of any of its rights under this Agreement is only effective if it is in a signed written notice to the other Party and then only to the extent specified in that notice.

## 9. Taxes, duties and government charges

9.1 The Grantee agrees to pay all taxes, duties and government charges imposed or levied in Australia or overseas in connection with the performance of this Agreement, except as provided by this Agreement.

9.2 If Goods and Services Tax (GST) is payable by a supplier on any supply made under this Agreement, the recipient of the supply will pay to the supplier an amount equal to the GST payable on the supply, in addition to and at the same time that the consideration for the supply is to be provided under this Agreement.

9.3 The Parties acknowledge and agree that they each:

- (a) are registered for GST purposes;

- (b) have quoted their Australian Business Number to the other; and
- (c) must notify the other of any changes to the matters covered by this clause.

9.4 The Grantee agrees that the Commonwealth will issue it with a recipient created tax invoices for any taxable supplies it makes under this Agreement.

9.5 The Grantee agrees not to issue tax invoices in respect of any taxable supplies.

9.6 If the Grantee is not, or not required to be, registered for GST, then:

- (a) clauses 9.3(a), 9.4 and 9.5 do not apply; and
- (b) the Grantee agrees to notify the Commonwealth in writing within 7 days of becoming registered for GST if during the term of the Agreement it becomes, or is required to become, registered for GST.

## 10. Spending the Grant

10.1 The Grantee agrees to spend the Grant for the purpose of performing the Activity and otherwise in accordance with this Agreement.

10.2 Within 90 days after the Project End Date, the Grantee agrees to provide the Commonwealth with an independently audited financial acquittal report verifying that the Grant has been spent in accordance with this Agreement.

10.3 The reports under clause 10.2 must be audited by:

- (a) a Registered Company Auditor registered under the *Corporations Act 2001* (Cth); or
- (b) a certified Practising Accountant; or
- (c) a member of the Institute of Public Accountants; or
- (d) a member of Chartered Accountants Australia and New Zealand;

who is not a principal member, shareholder, officer or employee of the Grantee or a related body corporate.

## 11. Repayment

11.1 If any amount of the Grant:

- (a) has been spent other than in accordance with this Agreement; or
- (b) is additional to the requirements of the Activity

then the Commonwealth may, by written notice:

- (c) require the Grantee to repay that amount to the Commonwealth;
- (d) require the Grantee to deal with that amount as directed by the Commonwealth; or
- (e) deduct the amount from subsequent payments of the Grant or amounts payable under another agreement between the Grantee and the Commonwealth.

11.2 If the Commonwealth issues a notice under this Agreement requiring the Grantee to repay a Grant amount:

- (a) the Grantee must do so within the time period specified in the notice;
- (b) the Grantee must pay interest on any part of the amount that is outstanding at the end of the time period specified in the notice until the outstanding amount is repaid in

full; and

- (c) the Commonwealth may recover the amount and any interest under this Agreement as a debt due to the Commonwealth without further proof of the debt being required.

## 12. Record keeping

12.1 The Grantee agrees to keep financial accounts and other records that:

- (a) detail and document the conduct and management of the Activity;
- (b) identify the receipt and expenditure of the Grant separately within the Grantee's accounts and records so that at all times the Grant is identifiable;
- (c) enable all receipts and payments related to the Activity to be identified and reported.

12.2 The Grantee agrees to keep the records for five years after the Completion Date or such other time specified in the Grant Details and provide copies of the records to the Commonwealth upon request.

## 13. Reporting and liaison

13.1 The Grantee agrees to provide the Reporting Material specified in the Grant Details to the Commonwealth.

13.2 In addition to the obligations in clause 13.1, the Grantee agrees to:

- (a) liaise with and provide information to the Commonwealth as reasonably required by the Commonwealth; and
- (b) comply with the Commonwealth's reasonable requests, directions, or monitoring requirements,

in relation to the Activity.

13.3 If the Commonwealth acting reasonably has concerns regarding the performance of the Activity or the management of the Grant, the Commonwealth may by written notice require the Grantee to provide one or more additional reports, containing the information and by the date(s) specified in the notice.

13.4 The Grantee acknowledges that the giving of false or misleading information to the Commonwealth is a serious offence under the *Criminal Code Act 1995* (Cth).

## 14. Privacy

14.1 When dealing with Personal Information in carrying out the Activity, the Grantee agrees:

- (a) to comply with the requirements of the *Privacy Act 1988* (Cth);
- (b) not to do anything which, if done by the Commonwealth, would be a breach of an Australian Privacy Principle;
- (c) to ensure that any of the Grantee's subcontractors or personnel who deal with Personal Information for the purposes of this Agreement are aware of the requirements of the *Privacy Act 1988* (Cth) and the Grantee's obligations under this clause;
- (d) to immediately notify the Commonwealth if the Grantee becomes aware of an actual or possible breach of this clause by the Grantee or any of the Grantee's subcontractors or personnel.

14.2 In carrying out the Activity, the Grantee agrees not to send any Personal Information outside of Australia without the Commonwealth's prior written approval. The Commonwealth may impose any conditions it considers appropriate when giving its approval.

## 15. Confidentiality

15.1 The Parties agree not to disclose each other's confidential information without the other Party's prior written consent unless required or authorised by law or Parliament to disclose.

15.2 The Commonwealth may disclose the Grantee's confidential information where;

- (a) the Commonwealth is providing information about the Activity or Grant in accordance with Commonwealth accountability and reporting requirements;
- (b) the Commonwealth is disclosing the information to a Minister of the Australian Government, a House or Committee of the Commonwealth Parliament; or
- (c) the Commonwealth is disclosing the information to its personnel or another Commonwealth agency where this serves the Commonwealth's legitimate interests.

## 16. Insurance

16.1 The Grantee agrees to maintain adequate insurance for as long as any obligations remain in connection with this Agreement and provide proof of insurance to the Commonwealth upon request.

## 17. Intellectual property

17.1 The Grantee owns the Intellectual Property Rights in Material created by the Grantee as a result of undertaking the Activity.

17.2 The Grantee provides the Commonwealth a permanent, non-exclusive, irrevocable, royalty-free licence to use, modify, communicate, publish, adapt and sub-license the Reporting Material for Commonwealth Purposes.

17.3 The licence in clause 17.2 does not apply to Activity Material.

17.4 This Agreement does not affect the ownership of Intellectual Property Rights in Existing Material.

## 18. Dispute resolution

18.1 The Parties agree not to initiate legal proceedings in relation to a dispute arising under this Agreement unless they have first tried and failed to resolve the dispute by negotiation.

18.2 Unless clause 18.3 applies, the Parties agree to continue to perform their respective obligations under this Agreement when a dispute exists.

18.3 The Parties may agree to suspend performance of the Agreement pending resolution of the dispute.

18.4 Failing settlement by negotiation in accordance with clause 18.1, the Parties may agree to refer the dispute to an independent third person with power to intervene and direct some form of resolution, in which case the Parties will be bound by that resolution. If the Parties do not agree to refer the dispute to an independent third person, either Party may initiate legal proceedings.

18.5 Each Party will bear their own costs in complying with this clause 18, and the Parties will share equally the cost of any independent third person engaged under clause 18.4.

18.6 The procedure for dispute resolution under this clause does not apply to any action relating to termination, cancellation or urgent interlocutory relief.

## 19. Reduction, Suspension and Termination

### 19.1 Reduction in scope of agreement for fault

19.1.1 If the Grantee does not comply with an obligation under this Agreement and the Commonwealth believes that the non-compliance is incapable of remedy, or if the Grantee has failed to comply with a notice to remedy, the Commonwealth may by written notice reduce the scope of the Agreement.

19.1.2 The Grantee agrees, on receipt of the notice of reduction, to:

- (a) stop or reduce the performance of the Grantee's obligations as specified in the notice;
- (b) take all available steps to minimise loss resulting from the reduction;
- (c) continue performing any part of the Activity or the Agreement not affected by the notice if requested to do so by the Commonwealth;
- (d) report on, and return any part of the Grant to the Commonwealth, or otherwise deal with the Grant, as directed by the Commonwealth.

19.1.3 In the event of reduction under clause 19.1.1, the amount of the Grant will be reduced in proportion to the reduction in the scope of the Agreement.

### 19.2 Suspension

19.2.1 If:

- (a) the Grantee does not comply with an obligation under this Agreement and the Commonwealth believes that the non-compliance is capable of remedy
- (b) the Commonwealth reasonably believes that the Grantee is unlikely to be able to perform the Activity or manage the Grant in accordance with this Agreement; or
- (c) the Commonwealth reasonably believes that there is a serious concern relating to this Agreement that requires investigation;

the Commonwealth may by written notice:

- (d) immediately suspend the Grantee from further performance of the Agreement (including expenditure of the Grant); and/or
- (e) require that the non-compliance be remedied, or the investigation be completed, within the time specified in the notice.

19.2.2 If the Grantee:

- (a) remedies the non-compliance or inability specified in the notice to the Commonwealth's reasonable satisfaction, or the Commonwealth reasonably concludes that the concern is unsubstantiated, the Commonwealth may direct the Grantee to recommence performing the Activity; or
- (b) fails to remedy the non-compliance or inability within the time specified, or the Commonwealth reasonably concludes that the concern is likely to be substantiated, the Commonwealth may reduce the scope of the Agreement in accordance with clause 19.1 or terminate the Agreement immediately by giving a second notice in

accordance with clause 19.3.

### 19.3 Termination for fault

19.3.1 The Commonwealth may terminate this Agreement by notice where the Grantee has:

- (a) failed to comply with an obligation under this Agreement and the Commonwealth believes that the non-compliance is incapable of remedy or where clause 19.2.2(b) applies;
- (b) provided false or misleading statements in relation to the Grant; or
- (c) become bankrupt or insolvent, entered into a scheme of arrangement with creditors, or come under any form of external administration.

19.3.2 The Grantee agrees, on receipt of the notice of termination, to:

- (a) stop the performance of the Grantee's obligations;
- (b) take all available steps to minimise loss resulting from the termination; and
- (c) report on, and return any part of the Grant to the Commonwealth, or otherwise deal with the Grant, as directed by the Commonwealth.

## 20. Cancellation or reduction for convenience

20.1 The Commonwealth may cancel or reduce the scope of this Agreement by notice, due to:

- (a) a change in government policy; or
- (b) a Change in the Control of the Grantee which the Commonwealth reasonably believes will negatively affect the Grantee's ability to comply with this Agreement.

20.2 On receipt of a notice of reduction or cancellation under this clause, the Grantee agrees to:

- (a) stop or reduce the performance of the Grantee's obligations as specified in the notice; and
- (b) take all available steps to minimise loss resulting from that reduction or cancellation; and
- (c) continue performing any part of the Activity or the Agreement not affected by the notice if requested to do so by the Commonwealth;
- (d) report on, and return any part of the Grant to the Commonwealth, or otherwise deal with the Grant, as directed by the Commonwealth.

20.3 In the event of reduction or cancellation under this clause, the Commonwealth will be liable only to:

- (a) pay any part of the Grant due and owing to the Grantee under this Agreement at the date of the notice; and
- (b) reimburse any reasonable and substantiated expenses the Grantee unavoidably incurs that relate directly and entirely to the reduction in scope or cancellation of the Agreement.

20.4 In the event of reduction, the amount of the Grant will be reduced in proportion to the reduction in the scope of the Agreement.

20.5 The Commonwealth's liability to pay any amount under this clause is:

- (a) subject to the Grantee's compliance with this Agreement; and

- (b) limited to an amount that when added to all other amounts already paid under the Agreement will not exceed the total amount of the Grant.

20.6 The Grantee will not be entitled to compensation for loss of prospective profits or benefits that would have been conferred on the Grantee but for the cancellation or reduction in scope of the Agreement under clause 20.1.

20.7 The Commonwealth will act reasonably in exercising its rights under this clause.

## 21. Survival

21.1 The following clauses survive termination, cancellation or expiry of this Agreement:

- clause 10 (Spending the Grant);
- clause 11 (Repayment);
- clause 12 (Record keeping);
- clause 13 (Reporting);
- clause 14 (Privacy);
- clause 15 (Confidentiality);
- clause 16 (Insurance)
- clause 17 (Intellectual property);
- Clause 19 (Reduction, Suspension and Termination);
- clause 21 (Survival);
- clause 22 (Definitions); and
- any other clause which expressly or by implication from its nature is meant to survive.

## 22. Definitions

22.1 In this Agreement, unless the contrary appears:

- **Activity** means the activities described in the Grant Details.
- **Activity Material** means any Material, other than Reporting Material, created or developed by the Grantee as a result of the Activity and includes any Existing Material that is incorporated in or supplied with the Activity Material.
- **Agreement** means the Grant Details, Supplementary Terms (if any), the Commonwealth Standard Grant Conditions and any other document referenced or incorporated in the Grant Details.
- **Australian Privacy Principle** has the same meaning as in the *Privacy Act 1988* (Cth).
- **Change in the Control** means any change in any person(s) who directly exercise effective control over the Grantee.
- **Commonwealth** means the Commonwealth of Australia as represented by the Commonwealth entity specified in the Agreement and includes, where relevant, its officers, employees, contractors and agents.
- **Commonwealth Standard Grant Conditions** means this document.
- **Commonwealth Purposes** includes the following:

- (a) the Commonwealth verifying and assessing funding proposals, including a grant application;
- (b) the Commonwealth administering, monitoring, reporting on, auditing, publicising and evaluating a grant program or exercising its rights under this Agreement;
- (c) the Commonwealth preparing, managing, reporting on, auditing and evaluating agreements, including this Agreement;
- (d) the Commonwealth developing and publishing policies, programs, guidelines and reports, including Commonwealth annual reports;

but in all cases:

- (e) excludes the commercialisation (being for-profit use) of the Material by the Commonwealth.

- **Completion Date** means the date or event specified in the Grant Details.
- **Existing Material** means Material developed independently of this Agreement that is incorporated in or supplied as part of Reporting Material.
- **Grant** means the money, or any part of it, payable by the Commonwealth to the Grantee for the Activity as specified in the Grant Details and includes any interest earned on that money.
- **Grantee** means the legal entity other than the Commonwealth specified in the Agreement and includes, where relevant, its officers, employees, contractors and agents.
- **Grant Details** means the document titled Grant Details that forms part of this Agreement.
- **Intellectual Property Rights** means all copyright, patents, registered and unregistered trademarks (including service marks), registered designs, and other rights resulting from intellectual activity (other than moral rights under the *Copyright Act 1968* (Cth)).
- **Material** includes documents, equipment, software (including source code and object code versions), goods, information and data stored by any means including all copies and extracts of them.
- **Party** means the Grantee or the Commonwealth.
- **Personal Information** has the same meaning as in the *Privacy Act 1988* (Cth).
- **Records** includes documents, information and data stored by any means and all copies and extracts of the same.
- **Reporting Material** means all Material which the Grantee is required to provide to the Commonwealth for reporting purposes as specified in this Agreement, including the Grant Details, and includes any Existing Material that is incorporated in or supplied with the Reporting Material.

## Signatures

Executed as an agreement:

Commonwealth

Signed for and on behalf of the Commonwealth of Australia as represented by the Department of Health

Name (print)	S 22
Position (print)	Acting Assistant Secretary
Signature	S 22
Date	23 July 2018
Witness name (print)	S 22
Signature	S 22
Date	23 July 2018

## Grantee

Name of Company	National Stroke Foundation ABN: 42 006 173 379 ACN: 006 173 379
Director name (print)	S 22
Signature	S 22
Date	18/7/18
Director/ Company Secretary name (print)	S 22
Signature	S 22
Date	23 July 2018

## Schedule 2 Reporting templates

### Appendix 1

#### Accelerated Research program - progress report

Submit your completed report to [arp@industry.gov.au](mailto:arp@industry.gov.au)

Grantee name	[organisation name]
Project title	[project title]
Project number	[project number]
Reporting period	[reporting period start date] to [reporting period end date]

#### 1. Project progress

- a. Complete the following table, updating for all milestones shown in the Activity Schedule of your grant agreement. Add rows as required.

No	Milestone description	Agreed completion date	Actual /anticipated completion date	Milestone progress (% complete) at end of reporting period
	[milestone 1 name]	dd/mm/yy		
	[milestone 2 name]	dd/mm/yy		
	[milestone 3 name]	dd/mm/yy		
	[milestone 4 name]	dd/mm/yy		

- b. Describe the eligible activities you completed during this reporting period, including your progress against milestones and any outcomes achieved. If applicable, comment on why your progress is delayed.

- c. Attach evidence to demonstrate your progress against project milestones this reporting to date. List the attached documents below against the relevant activity/s, or provide web links for any publicly available information.

- d. Is the overall project proceeding in line with your project plan and grant agreement?  yes  no

If no, identify any changes or anticipated issues. Comment on any impacts on project timing and outcomes and how you expect to manage these.

- e. Are there any planned events relating to the project that you are required to notify us about in accordance with your agreement?  yes  no

If yes, please provide details of the event including date, time, purpose of the event and key stakeholders expected to attend.

## 2. Eligible expenditure summary

- a. Complete the following table to show:
- i. total eligible expenditure incurred on the project prior to this reporting period
  - ii. eligible expenditure incurred in this reporting period
  - iii. estimated eligible expenditure for the remainder of the project.

If you are registered for GST, enter GST exclusive figures. If you are not registered for GST, enter GST inclusive figures. We may ask you to provide evidence of costs incurred.

Refer to the Accelerated Research grant opportunity guidelines or contact us if you have any questions about eligible expenditure.

Eligible project expenditure	Total
i. Eligible expenditure incurred prior to this reporting period	\$
ii. Eligible expenditure incurred this reporting period	\$
iii. Estimated expenditure for next reporting period	\$
iv. Estimate for remaining reporting periods in current financial year (if applicable)	\$
v. Estimated total expenditure in [20xx-xx]	\$
vi. Estimated total expenditure in [20xx-xx]	\$
vii. Estimated total expenditure in [20xx-xx]	\$
viii. Total estimate for project	\$

- b. Briefly explain the reason for any changes between the forecast and actual expenditure for the current reporting period, and any significant changes to the forecast budget for the remainder of the project.

c. Is the project expenditure broadly in line with the activity budget in the grant agreement?  yes  no

If no, explain the reasons.

### 3. Bank account details

Have your bank account details changed since your last payment?  yes  no

If yes, we will provide you with a form to complete your new bank details.

### 4. Certification

I .....being a person duly authorised by the grantee hereby certify that:

the information in this report is accurate, complete and not misleading and that I understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).

the activities identified above are for the purposes stated in the grant agreement.

I am aware of the grantee's obligations under their grant agreement, including the need to keep the Commonwealth informed of any circumstances that may impact on the objectives, completion and/or outcomes of the agreed project.

I am aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Signed .....Date

[Position/ title]

## Appendix 2

### Accelerated Research program - end of project report

Submit your completed report to [arp@industry.gov.au](mailto:arp@industry.gov.au)

Grantee name	[organisation name]
Project title	[project title]
Project number	[project number]
Reporting period	[reporting period start date] to [reporting period end date]

#### 5. Project achievements

- d. Complete the following table, updating for all milestones shown in the Activity Schedule of your grant agreement. Add rows as required.

No	Milestone description	Agreed completion date	Actual /anticipated completion date	Milestone progress (% complete) by the project end date
(f)	[milestone 1 name]	dd/mm/yy		
(g)	[milestone 2 name]	dd/mm/yy		
(h)	[milestone 3 name]	dd/mm/yy		
(i)	[milestone 4 name]	dd/mm/yy		

- e. Briefly outline the project milestones and activities completed by the project end date. If applicable, comment on why all milestones/activities were not completed by the project end date.

- f. Attach evidence to demonstrate successful completion of your project. List the attached documents below against the relevant activity/s, or provide web links for any publicly available information.

#### 6. Project outcomes

- g. Outline the project outcomes achieved by the project end date.

- h. Do the achieved project outcomes align with those specified in the grant agreement?  yes  no

If no, explain why.

- i. Attach copies of any published reports and promotional material, relating to the project, and list them below.

- j. Are there any planned events relating to the project that you are required to notify us about in accordance with your agreement?  yes  no

If yes, provide details of the event including date, time, purpose of the event and key stakeholders expected to attend.

### 7. Project benefits

- k. What benefits has the project achieved?

- l. What ongoing impact will the project have?

- m. Did the project result in any unexpected benefits?  yes  no

If yes, explain why.

- n. Is there any other information you wish to provide about your project?  yes  no

If yes, provide details.

### 8. Total eligible project expenditure

- o. Complete the following table, showing the total actual eligible expenditure incurred on the project. If you are registered for GST, enter GST exclusive figures. If you are not registered for GST, enter GST inclusive figures. We may ask you to provide evidence of costs incurred.

Refer to the Accelerated Research grant opportunity guidelines or contact us if you have any questions about eligible expenditure.

Eligible expenditure Items	Total
Plant and Equipment	\$
Purchase of Materials	\$
Labour	\$
Contract Expenditure	\$
Travel Expenditure	\$
Other Eligible Expenditure	\$
<b>Total Project Costs</b>	<b>\$</b>

p. Was the expenditure incurred in accordance with the activity budget in  yes  no the grant agreement?

If no, explain the reason for a project underspend or overspend, or any other significant changes to the budget.

### 9. Bank account details

Have your bank account details changed since your last payment?  yes  no

If yes, we will provide you with a form to complete your new bank details.

### 10. Certification

I .....being a person duly authorised by the grantee hereby certify that:

the information in this report is accurate, complete and not misleading and that I understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).

the grant was spent in accordance with the grant agreement.

I am aware of the grantee's obligations under their grant agreement, including survival clauses.

I am aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Signed .....Date

[Position/ title]

## Appendix 3

A template and related guidance for this report will be available on [business.gov.au](http://business.gov.au).

**Archived:** Wednesday, 18 March 2026 3:59:13 PM

**From:** [Research](#)

**Mail received time:** Mon, 7 Jun 2021 12:24:35

**Sent:** Mon, 7 Jun 2021 02:23:58

**To:** [Research Accelerated Research Program](#)

**Cc:** S 22

**Subject:** RE: National Stroke Foundation EPCD Grant Agreement Variation [SEC=OFFICIAL:Sensitive]

**Importance:** Normal

**Sensitivity:** None

**Attachments:**

[2021-06 Attachment B - Stroke Foundation Agreement of Variation.pdf](#);

---

Dear S 22

Thank you so much and please find attached our signed copy of the agreement of variation.

We look forward to hearing from you in due course.

Warm regards,

S 22

S 22

Research Administration & Compliance Officer

**Stroke Foundation**

\intbl\itap4Level 7, 461 Bourke St\intbl\itap4,\intbl\itap4Melbourne\intbl\itap4\intbl\itap4VIC\intbl\itap4\intbl\itap43000

\intbl\itap4D 03 9918 7215\intbl\itap4 >\intbl\itap4T 03 9670 1000

[research@strokefoundation.org.au](mailto:research@strokefoundation.org.au)

**Stroke Foundation**

StrokeLine: 1800 STROKE (1800 787 653)



**Please note:** Stroke Foundation services are fully operational with appropriate COVID19 safe plans ensuring we are there when and where the stroke community needs us most. The health and well being of our people, our community and supporters remains out highest priority as we strive to prevent stroke, save lives and enhance recovery.





The Stroke Foundation acknowledges the ancestors and traditional custodians of the land on which our offices stand and pay respect to Elders past, present and emerging.

This e-mail may contain confidential information. This message and any attachments are for the addressee only. If you have received it in error, please notify the sender. The legal effect of this e-mail is subject to its compliance with the Stroke Foundation. All e-mails sent to the Stroke Foundation may be monitored, stored and used by the company for any lawful purpose. The Stroke Foundation prohibits transmission of inappropriate material to its e-mail addresses. Any personal comments contained within this message are those of the sender not of the Stroke Foundation. The Stroke Foundation provides no assurance that this e-mail or any attachments are free of software viruses or that the opening or execution of the attachment will not cause harm to the computer systems of the Recipient and accepts no liability whatsoever for any damage of whatsoever nature, caused by such a virus.

**From:** Accelerated Research Program <[arp@industry.gov.au](mailto:arp@industry.gov.au)>

**Date:** Thursday, 3 June 2021 at 11:34 AM

**To:** S 22 <[@strokefoundation.org.au](mailto:@strokefoundation.org.au)>

**Cc:** Accelerated Research Program <[arp@industry.gov.au](mailto:arp@industry.gov.au)>

**Subject:** National Stroke Foundation EPCD Grant Agreement Variation [SEC=OFFICIAL:Sensitive]

Dear S 22,

After some consideration, the Dept. of Health has reviewed the recent progress report submission and is proposing the attached agreement of variation.

The agreement of variation covers the extension of project duration requested and is also looking to approve payment of the remaining funding associated with the project for this financial year.

In order to extend the project and pay all remaining funds for the project, an executed agreement of variation is required.

Upon review of the proposed agreement of variation, please provide a signed copy of the attached agreement of variation for Dept. of Health to execute as soon as possible.

Please be aware that there are a number of administrative processes involved with executing the agreement of variation and processing the remaining payments for the project, so some urgency in signing is required.

If you have any questions, please let me know. Otherwise, we'll await the signed agreement of variation to provide to the Dept. of Health to execute.

Sincerely,

S 22

Business Grants Hub

S 22


| S 22

[@industry.gov.au](mailto:industry.gov.au)

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**Department of Industry, Science, Energy and Resources** | [www.industry.gov.au](http://www.industry.gov.au)

**Supporting economic growth and job creation for all Australians**

 *The department acknowledges the Traditional Owners of the country throughout Australia and their continuing connection to the land, sea and community. We pay our respect to them and their cultures and to the elders past and present.*

\qcOFFICIAL: Sensitive

# Department of Health

## Agreement of Variation

Commonwealth of Australia (**Commonwealth**)

National Stroke Foundation (**Grantee**)

---

## Details

Date	7	/	June	/	2021
	day		month		year

## Parties

Name	The Commonwealth of Australia as represented by the Department of Health
ABN	83 605 426 759
Short form name	<b>Commonwealth</b>
Address details	Sirius Building, 23 Furzer Street  Woden Town Centre ACT 2606  GPO Box 9848  Canberra ACT 2601

Name	National Stroke Foundation
ABN	42 006 173 379
Short form name	<b>Grantee</b>
Address details	<b>Physical</b> National Stroke Foundation Level 7, 461 Bourke Street MELBOURNE VIC 3000 <b>Postal</b> National Stroke Foundation Level 7, 461 Bourke Street MELBOURNE VIC 3000

## Background

- A. The Commonwealth and the Grantee entered into a grant agreement for *two distinct elements*: *Australian Living Guidelines for Stroke Management, and "Return to life, return to work"*. A *targeted clinical research investment in stroke recovery for young survivors*. This project is under the Medical Research Future Fund (MRFF) Emerging Priorities and Consumer Driven Research (EPCDR) Initiative dated 23 July 2018.
- B. No previous Variation Agreement has been recorded.
- C. The Commonwealth and the Grantee have agreed to vary the terms of the Grant Agreement in accordance with this Variation Agreement.
- D. The parties acknowledge that this Variation Agreement satisfies all requirements in the Grant Agreement for a legally binding variation.

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# Agreed terms

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## 1. Defined terms and interpretation

### 1.1 Defined terms

In this Variation Agreement, unless the contrary intention appears:

- (a) a word or expression defined or referred to in the Grant Agreement has the meaning given to it in the Grant Agreement;
- (b) **Effective Date** means the date that the last party executes this Variation Agreement;
- (c) **Grant Agreement** means the grant agreement described in paragraph A of the Background including any variations;
- (d) **Variation Agreement** means this agreement of variation, including all annexures and schedules to it.

## 2. Variation to Grant Agreement

On and with effect from the Effective Date, the Grant Agreement is varied as set out in Schedule I to this Variation Agreement.

## 3. Affirmation of Grant Agreement

- (a) The parties affirm in all other respects the covenants and conditions in the Grant Agreement as varied by this Variation Agreement.
- (b) The Grant Agreement, as varied by this Variation Agreement, comprises the entire agreement between the parties.
- (c) The parties acknowledge and agree that the Grant Agreement as varied by this Variation Agreement is and continues to be in full force and effect.

## 4. Consideration

In consideration of the Commonwealth entering into this Variation Agreement, the Grantee pays the sum of \$1 to the Commonwealth.

## 5. Costs and GST

- (a) Each party must meet or pay its own costs and expenses in respect of the preparation, negotiation, execution and completion of this Variation Agreement.
- (b) If GST is payable on any supply made under or in connection with this Variation Agreement, the recipient of the supply must pay to the supplier an additional amount equal to the GST payable on the supply provided that the supplier has given the recipient a tax invoice for the supply.
- (c) The Grantee must pay any stamp duties and registration or other fees (including fines, penalties and interest relating to such duties and fees) which are payable or are assessed by a relevant government body or other person to be payable in relation to this document or any transaction contemplated by it.

## 6. Miscellaneous

### 6.1 Counterparts

This Variation Agreement may be executed in counterparts. All executed counterparts constitute one document. A party may execute this Variation Agreement by signing any counterpart.

### 6.2 Governing law and jurisdiction

This Variation Agreement is governed by the law of the Australian Capital Territory and each party irrevocably submits to the non-exclusive jurisdiction of the courts of the Australian Capital Territory.

# Signing page

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**EXECUTED** as an Agreement.

Signed for and on behalf of the  
**Commonwealth of Australia as  
represented by the Department of  
Health** by its duly authorised delegate

S 22

Signature or delegate

S 22

\_\_\_\_\_  
Name of delegate (print)

Chief Executive Officer  
Health and Medical Research Office

\_\_\_\_\_  
Position of delegate (print)

Date 7 June 2021

S 22

**Executed by National Stroke Foundation**  
in accordance with Section 126 of the  
*Corporations Act 2001* by its authorised  
representative

Signature of authorised representative  
(Please delete as applicable)

S 22

\_\_\_\_\_  
Name of authorised representative (print)

**VICE PRESIDENT**

\_\_\_\_\_  
Capacity of authorised representative (print)

Date 07/06/2021

# Schedule 1 – Variation to Grant Agreement

## Clause C is varied

Clause C is varied by deleting the clause and replacing it with the following:

### C. Duration of the Grant

The Activity starts on 23 July 2018 and ends on 31 December 2022, which is the **Activity Completion Date**.

The Agreement ends on 30 June 2023, which is the **Agreement End Date**.

#### Activity Schedule - Australian Living Guidelines for Stroke Management

No.	Title and description	Due date
1	Project start date	30 July 2018
2	Project Evaluation – create evaluation plan	30 September 2018
3	Establish platform and methods – design and build	31 December 2018
4	Create and maintain living guidelines – initial update	1 April 2019
5	Engage the stroke community, including the public, health professionals and guideline development groups – initial mechanisms established	1 April 2019
6	Establish platform and methods – test and refine	31 December 2019
7	Create and maintain living guidelines – ongoing until project end	31 December 2022
8	Engage the stroke community, including the public, health professionals and guideline development groups – ongoing until project end	31 December 2022
9	Project end date	31 December 2022

#### Activity Schedule - “Return to life, return to work”

No.	Title and description	Due date
1	Project start date	30 July 2018

No.	Title and description	Due date
2	Call for research applications concludes	31 December 2018
3	Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30 June 2019
4	Training of staff at trial sites concludes	31 December 2019
5	Publication of study protocol and statistical analysis plan	30 April 2022
6	Patient recruitment concludes	30 April 2022
7	Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31 December 2022
8	Clinical Trial close out, closure of sites, results written up and presented, publication plan	31 December 2022
9	Project end date	31 December 2022

#### Clause D is varied

Clause D is varied by deleting the clause and replacing it with the following:

#### D. Payment of the Grant

The total amount of the Grant is \$2,500,000 (plus GST if applicable).

The Grant will be provided at up to 100 per cent of eligible expenditure as defined in the Grant Opportunity Guidelines subject to satisfactory progress towards milestones and availability of Program funds.

The Grant will be paid in accordance with clause ST2.

The Grant will be paid according to the following schedule. Payments are subject to satisfactory progress on the Project and compliance by the Grantee with its obligations under this Agreement.

Payment event	Payment amount (GST exclusive)	Payment date
		July 2018
		February 2019
		February 2020
		June 2021
		February 2022

S 47G

S 47G

		<b>Payment date</b>
		March 2023
Total	\$2,500,000	

**Invoicing**

The Grantee agrees to allow the Commonwealth to issue it with a Recipient Created Tax Invoice (RCTI) for any taxable supplies it makes in relation to the Activity.

**Clause E is varied**

Clause E is varied by deleting the clause and replacing it with the following:

**E. Reporting**

The Grantee agrees to provide the following reports to the Commonwealth representative in accordance with the Reporting Templates (Schedule 2).

Report type	Period start date	Period end date	Agreed evidence	Due date
Progress report	Project start date	31 December 2018	Progress report	31 January 2019
Progress report	1 January 2019	31 December 2019	Progress report	31 January 2020
Progress report and risk management plan	1 January 2020	30 June 2020	Progress report	31 July 2020
Progress report	1 July 2020	31 December 2020	Progress report	31 January 2021
Progress report	1 January 2021	31 December 2021	Progress report	31 January 2022
End of project report	Project start date	31 December 2022	Satisfactory completion of the final report template	31 March 2023
Independent audit report	Project start date	31 December 2022	Satisfactory report completed by independent auditor	31 March 2023

During the Agreement period, we may ask you for ad-hoc reports on your project. You must provide these reports in the timeframes notified by the Commonwealth.

**Clause ST2.1 is varied**

Clause ST2.1 is varied by deleting the clause and replacing it with the following:

**ST 2. Activity budget**

ST2.1 The Grantee agrees to use the Grant and undertake the Activity consistently with the activity budget in the following table:

**S 47G**

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Figures in the above table are GST inclusive amounts less GST credits that can be claimed in relation to the expenditure.

1975-76

1976-77

1977-78

1978-79

1979-80

1980-81

1981-82

1982-83

1983-84

1984-85

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1987-88

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2012-13

2013-14

2014-15

2015-16

2016-17

2017-18

2018-19

2019-20

2020-21

**Australian Government**

**FOR OFFICIAL USE ONLY**

**Department of Industry, Science,  
Energy and Resources**

Department of Industry,  
Science, Energy and Resources  
GPO Box 2013  
CANBERRA ACT 2601  
e: ARP@industry.gov.au  
w: business.gov.au  
ABN: 74 599 608 295

Program Delegate  
Medical Research Future Fund (MRFF)  
Emerging Priorities and Consumer Driven Research (EPCDR) Initiative

**For Action**

**Subject: AGREEMENT VARIATION REQUESTS: AMENDMENT OF FOUR EMERGING PRIORITIES AND CONSUMER DRIVEN RESEARCH INITIATIVE AGREEMENTS WITH FINAL PAYMENTS IN FY2020/21**

**Timing: May 2021**

**PROPOSED ACTION**

1. That the Department of Health consider the proposed four identical Grant Agreement variation requests to allow outstanding FY2020/21 payments to be made for four Emerging Priorities and Consumer Driven Research Initiative (EPCDR) grant projects as listed below; and
2. If this request is approved, the Department of Health consider the four attached draft Agreements of Variation and authorise the Department of Industry, Science, Energy and Resources (DISER) to issue these to the relevant grantees for signature.

The four EPCD Grant Agreement of Variations relate to the following projects:

1. **S 22**
2. **National Stroke Foundation (EPCD000019)**
3. **S 22**
4. **S 22**

**Background:**

As a risk mitigation measure during Grant Agreement (agreement) negotiation for a number of original EPCDR projects, final payments were linked to the provision of final reports in the associated agreements to allow accrual of payments into future years. Technically this did not change the date when annual allocation of committed funding fell due, but rather it was aimed at providing the Department of Health (Health) an opportunity to accrue those funds until the end of a project in the instance the grantee was deemed to be very high risk. It should be noted that for the more recent EPCDR projects this practise was abandoned as Health determined it did not align with the preferred annual commitment approvals, while the grantees were also not deemed to be of sufficiently high risk to warrant such a requirement.

The four grant EPCDR projects that feature in this minute all have final payments linked to provision of their final reports and without amendments to the associated agreements, all final payments would have to be accrued into future years. However, upon discussion with the policy team at Health - and similar to the rest of the EPCDR projects and grantees - the Business Grants Hub (BGH) are recommending that these applicants be viewed as low to medium risk and action taken to allow payment of current year grant funds instead of accruing. Note that the medium risk

rating specifically relates to the grantees being affected by Covid-19 and is mitigated through provision of revised project milestone timeframes utilising Covid-19 plans.

Upon discussion with all four grantees, and similar to most other EPCDR grantees, they have all requested extensions of time to their Activity Completion Date (project end date) due to the adverse impacts of COVID-19 and related restrictions.

BGH is therefore recommending that the same action is undertaken for all four affected EPCDR projects that allow final payments to be paid out according to the original commitment approval and not accrued, and that extensions of time to push out the project end dates by 18 months be supported. In order to allow these actions to occur – and they all fall in the FY2020/21 financial year - all four affected EPCDR agreements require variations to be finalised by mid-June 2021. Each individual project is listed below.

S 22

## 2. *National Stroke Foundation (EPCD000019)*

S 47G

The proposed variation extends the **Activity Completion Date** by 18 months to 31 December 2022 and also combines both FY2020/21 payments into one, linking it to the assessment that is currently under consideration by Health. It also adjusts the reporting schedule to account for the extension (see [Attachment B](#) –draft Agreement of Variation).

S 22

S 22

**Recommendation:**

The proposed extension to project end dates and related amendments of the reporting schedules and payment tables that are identical for all four EPCD grantees will enable payment of all the funding allocated in FY2020/21, allowing project outcomes to be met and alignment of payments to Health's original approved financial commitments. All project extensions have primarily been due to the pandemic and related adverse impacts on project activities, with the grantees considered to be low risk by BGH.

Under Clause 8.1 in Schedule 1 of the agreements, Health is able to approve the four requested variations that amend the original executed agreements. As such, it is recommended the attached draft Agreement of Variations be approved for issuing to the four EPCD grantees listed. However, if you do not approve this recommendation to vary the agreements please provide direction to undertake an alternative action at your earliest convenience so that funds are not required to be accrued – or at worst case, lost to the grantee.

If you need any further information on the options proposed, please feel free to contact S 22 from the team on (S 22

Kind regards,

S 22

Program Manager  
Business Grants Hub

24 May 2021

**ATTACHMENTS**

A: S 22

B: Draft Agreement of Variation – National Stroke Foundation (EPCD000019)

OFFICIAL

C: S 22

D: S 22

)

OFFICIAL

OFFICIAL: Sensitive



9 August 2022

S 22

Program Management and Delivery  
Business Grants Hub  
Department of Industry, Science, Energy and Resources

Registered Charity  
ABN 42 006 173 379  
Level 7, 461 Bourke Street  
Melbourne VIC 3000  
Telephone 03 9670 1000  
StrokeLine 1800 STROKE  
(1800 787 653)  
strokefoundation.org.au

Sent via email: [arp@industry.gov.au](mailto:arp@industry.gov.au)

Dear S 22

**RE: APPLICATION ID EPCD000019 (ARG73055)**

Thank you for your email dated 28 June 2022 confirming that a variation to the above grant agreement can be accepted for consideration by the Department of Health, under the [Medical Research Future Fund Grant Variation Policy \(published 20 May 2022\)](#).

Please accept this letter and supporting documentation as advised to formalise our request for a variation under point the 'Defer an in-process grant' variation due to 'external delays in the provision of research data or outcomes critical to progression of the grant'.

The current Deed of Variation (dated 7 June 2021) provides the Activity Schedules for the two distinct project outcomes of the above Grant Agreement, '*Australian Living Guidelines for Stroke Management*', and '*Return to life, return to work*' - a targeted clinical research investment in stroke recovery for young survivors. The '*Return to life, return to work*' project outcome has two associated clinical trials, '*Return to life or PESTO*', and '*Return to work*'.

As reported in January 2022, the project outcome, '*Australian Living Guidelines for Stroke Management*', is complete. The '*Return to work*' clinical trial is well-positioned for completion by the current project end date of 31 December 2022. The '*Return to life*' or PESTO clinical trial has been impacted by coronavirus pandemic (COVID-19) and so a 12-month 'defer an in-process grant' variation is requested to successfully complete this project outcome.

## 1. Rationale for variation

Since the '*Return to life, return to work*' clinical trials were commenced in 2019, the exceptional circumstances and impacts of the global COVID-19 pandemic have had far-reaching and ongoing effects. Clinical research during 2020-2021 was severely restricted and as a result, strategies to re-engage community participation in clinical trials have required innovative and supportive measures beyond original project plans. Both clinical trials funded by this grant have achieved remarkable progress to date,

despite these challenges – a view commonly held among research peers and Stroke Foundation’s networks.

### **Return to life trial: PESTO**

#### **Project progress**

The PESTO trial has reached a significant milestone in the reporting period captured by the ad hoc report submitted July 2022. That is, more than half of its required sample size has been reached (83 randomised participants/160 targeted ~ 52%). This significant participation level achieved demonstrates the continued importance of this trial for Australians who have been impacted in ‘returning to life’ and importantly, quality of life, after stroke.

Based on the current rate of recruitment, the trial would report inconclusive data if the project concluded in 2022 as per the current variation. The requested project duration variation is needed to allow the full benefit of these strategies to be realised and enable through additional time, the trial to reach its required sample size to provide a reliable answer to the unknown potential of this currently unproven treatment in Australia.

Please refer to the attached **Updated Project Plan** (Attachment A) to support this variation request for the PESTO trial.

#### **Budget**

The requested 12-month extension to 31 December 2023 is feasible to achieve within the allocated grant budget. This will be supported with a commitment of in-kind support from the PESTO trial’s administering institution, The Florey Institute of Neuroscience and Mental Health (The Florey), for the trial’s Principal Investigator, Professor Vincent Thijs to continue leading the trial until its objectives have been delivered.

Please refer to the attached **Updated Budget** (Attachment B) to support this variation request for the PESTO trial.

#### **Risk**

As identified in the progress reports, the main risk to the trial’s successful completion is recruitment. Risk mitigation strategies have been regularly reviewed with the PESTO Steering Committee and Stroke Foundation, including appropriate study protocol amendments and trial promotion activities (for example, social media including a trial participant interview to support peer-to-peer communication of the trial’s importance). The trial has successfully implemented statistically and Human Research Ethics Committee-supported amendments to the study protocol to date. These amendments have increased the participant inclusion criteria without compromising the original research question and study design which targets quality of life measures for working-age Australians post-stroke as the primary outcome. The last amendment to the trial’s inclusion criteria has been submitted for ethics approval in June 2022. As noted in the

ad hoc report submitted July 2022, the team anticipate this amendment will be approved by Austin Health ethics in August 2022.

Please refer to the attached **Updated Risk Management Plan** (Attachment C) to support this variation request for the PESTO trial.

S 22

## 2. Updated Budget

No additional funds are requested to support this project duration variation.

The updated Activity Budget table provided as Attachment B outlines the expenditure to date and the anticipated schedule for Stroke Foundation's release of the remaining grant funds allocated for the PESTO trial. This eligible expenditure aligns with the revised project timeline and acquittals of project expenditure. The existing budget and in-kind commitment of The Florey for the PESTO trial supports the project's extension with no cost impact to the agreed Activity Budget.

We note that the existing Deed of Variation dated 7 June 2021 contains an incorrect Activity Budget summary. We request the advice of your office for the opportunity to amend the Activity Budget in a subsequent Deed of Variation if approved.

## 3. Updated Milestones – Activity Schedule – “Return to life, return to work”

No.	Milestone – Title and Description	Current Agreed Date	Revised Due Date
1	Project start date	30 July 2018	no change

2	Call for research applications concludes	31 December 2018	no change
3	Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30 June 2019	no change
4	Training of staff at trial sites concludes	31 December 2019	no change
5	Publication of study protocol and statistical analysis plan	30 April 2022	30 June 2023
6	Patient recruitment concludes	30 April 2022	31 December 2023
7	Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31 December 2022	no change
8	Clinical Trial close out, closure of sites, results written up and presented, publication plan	31 December 2022	31 December 2023
9	Project end date	31 December 2022	31 December 2023

S 22

S 22

Thank you for your consideration of this request. If any additional information is required, please do not hesitate to contact me via email [research@strokefoundation.org.au](mailto:research@strokefoundation.org.au) or phone S 22

Sincerely,

S 22

**Executive Director Stroke Services and Research**  
Stroke Foundation



Thursday, March 19<sup>th</sup>, 2020

**RE: A Prospective multicentre, phase 2b randomised controlled double-blind trial, to determine the safety and efficacy of perispinal etanercept on quality of life at 28 days post treatment.**

Thank you for interest in the PESTO phase 2b trial.

As COVID-19 continues to spread throughout Australia over the last few days, and after extensive consultation with the Stroke Foundation and the Florey Clinical Trial Governance Committee, in the interest of participants' wellbeing, we need to temporarily delay the start of the PESTO trial.

We will continue to closely monitor the situation and keep you updated on when we will be able to start recruitment.

This was a difficult decision and we understand you may be disappointed with the delay but appreciate that we do not wish to compromise participants' health due to the COVID-19 outbreak.

Please let us know if you have any further questions.

Sincerely,

**PESTO Team**

**The Florey Institute of  
Neuroscience & Mental Health**  
245 Burgundy Street  
Heidelberg Victoria 3084  
Australia  
Email: [PESTO@florey.edu.au](mailto:PESTO@florey.edu.au)  
[www.florey.edu.au](http://www.florey.edu.au)



**Australian Government**  
**Department of Industry, Science and Resources**

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w: business.gov.au  
ABN: 74 599 608 295

Program Delegate  
Medical Research Future Fund (MRFF)  
Emerging Priorities and Consumer Driven Research (EPCDR) Initiative

**For Action**

**Subject: National Stroke Foundation – CONTRACT VARIATION REQUEST**

**Timing: September 2022**

**PROPOSED ACTION**

1. That the Department of Health and Aged Care consider the proposed grant agreement variation request; and
2. If the request is approved, the Department of Health and Aged Care consider the attached draft Variation Contract and authorise the Department of Industry, Science and Resources to issue the Variation Contract to the Grantee for signature.

The proposed Agreement of Variation relates to the following grant agreement:

Program: **MRFF – Emerging Priorities and Consumer Driven Research Initiative (EPCDR)**  
Grantee: National Stroke Foundation  
Grant no: EPCD000019 (MRFF)

**Background:**

On 23 July 2018, the Department of Health and Aged Care (Health) entered into a grant agreement (the Agreement) with the National Stroke Foundation (the grantee) for an Accelerated Research project (now called EPCDR Initiative) titled; *Guidelines for Stroke Management and Return to life, return to work - recovery for young survivors*.

Grant funding of up to \$2.5million was awarded with all funds paid in full (Attachment C). The project's original Project End Date was 30 June 2021, although on 7 June 2021 the parties varied the agreement to extend the Project End Date to 31 December 2022 (Attachment B).

The project has two distinct elements with two Activity Schedules:

S 22

Activity Schedule 2 – 'Return to Life, Return to Work' which has two elements:

- S 22
- Project 2 – ‘Return to Life’ clinical trial, also called *PESTO (Perispinal Etanercept to improve Stroke Outcomes)* (delayed)

On 14 June 2022 Health conditionally approved the Grantee’s progress report for the period 1 January 2021 to 31 December 2021 with a requirement to provide an additional ad hoc progress report for the period 1 January 2022 to 30 June 2022. The expectation was the additional report would provide more information and a strategy moving forward regarding delays to the ‘Return to Life – *PESTO*’ clinical trial.

On 29 July 2022 the grantee submitted the ad hoc progress report (Attachment I) as well as a formal request to vary the agreement to extend the project end date by 12 months to enable the *PESTO* clinical trial time to achieve the outcomes as per the agreement (Attachment E).

On the 19 August 2022 BGH submitted a variation package to Health on behalf of the grantee. Health subsequently requested that Activity Schedule 2 be split into two schedules; one for *Return to Work* and one for *Return to Life*. In revising the milestones for the new schedules the grantee also requested an extension for the completion of one milestone for *Return to work. Milestone 5: Publication of study protocol and statistical analysis plan*. The grantee explained that this milestone was delayed as some journals are taking six months for publication decision-making. They noted that the protocol was submitted for publication as at July 2022 and they anticipate this to be completed by 31 December 2022, which is in line with the project activity end date for this project.

S 47G

**Recommendation:**

That the Program Delegate consider this *in-progress grant variation request* to vary the Agreement and provide advice to BGH in relation to the following proposed option, or provide BGH with alternative guidance to action.

The Grantee has provided a clear explanation for the Covid-19 related delays and has given an assurance that the requested 12 month extension of time to the project period and revision of milestones is sufficient to allow completion of outcomes and objectives as outlined in Clause 1.3 of the Grant Opportunity Guidelines and Clauses A and B of the grant agreement.

BGH considers this variation request represents value for money and is an efficient, effective, economical and ethical use of resources that is consistent with the policies of the Commonwealth. As such, it is expected that this extension will allow the grantee to complete the agreed project milestones and outcomes as per the grant agreement.

Under Clause 8.1 in Schedule 1 of the Grant Agreement, it is recommended that Health approve the following changes (as per Attachment A - Draft Agreement of Variation) and agree to issuing the Agreement of Variation for signing by National Stroke Foundation to:

**Clause C – Duration of the Grant**

- Extend the Activity Completion Date (project end date) from 31 December 2022 to 31 December 2023
- Extend the Agreement End Date from 30 June 2023 to 30 June 2024

**Clause C – Activity Schedule – Return to Life, Return to Work**

- Split Activity Schedule – *Return to Life, Return to Work* into two schedules; *A:Return to Life* and *B:Return to work*
- Approve the amended Milestones, descriptions and due dates for the new schedules

**Clause E – Reporting**

- Add a Progress Report for the project activity period 1 January 2022 to 31 December 2022, due 31 January 2023
- Extend the due dates for the End of Project Report and Independent Audit from 31 March 2023 to 31 March 2024.

**ST3.1 Activity Budget**

- Update the Activity Budget to incorporate actual data and revised forecast expenditure for, FY 2018-19, FY 2019-20, FY2020-21, FY2021-22, FY2022-23, FY2023-24 consistent with new information provided by the Grantee (Attachment H).

Please advise whether the proposed variation is acceptable. If so, please provide approval to issue the attached draft Variation Contract.

Alternatively, please provide additional direction. We look forward to undertaking the administration of Health's recommendation as soon as possible.

If you need any further information on the options proposed, or for any other data in relation to this issue, please feel free to contact S 22 on S 22 .

Kind regards

S 22

S 22

Program Manager  
Business Grants Hub

27 September 2022

**ATTACHMENTS**

- A: Draft Agreement of Variation (revised)
- B: Agreement of Variation Executed 2021
- C: Grant Agreement Executed 2018
- D: Grant Opportunity Guidelines
- E: Request for Variation
- F: Project Plan
- G: Risk Management Plan
- H: Budget
- I: Ad Hoc Progress Report for the period 1 January to 30 June 2022

**Archived:** Friday, 13 March 2026 12:13:15 AM

**From:** S 22

**Mail received time:** Fri, 11 Dec 2020 18:11:21

**Sent:** Fri, 11 Dec 2020 05:26:19

**To:** S 22 [Accelerated Research Program](#)

**Cc:** S 22

**Subject:** FW: PESTO trial [SEC=OFFICIAL]

**Importance:** Normal

**Sensitivity:** None

**Attachments:**

[Stroke FA.PDF](#);

---

Hi S 22

Hope all is well.

S 22 who is our contact from the Stroke Foundation has indicated that they will need a request for extension as a result of COVID-19.

They were funded in total \$2.5 million over three years from 2018 to support the Stroke Foundation to develop Australian Living Guidelines for Stroke Management and undertake targeted clinical research on stroke recovery for young survivors ('Return to life, return to work'). There are two components of this project:

- 1) The Australian Living Guidelines for Stroke Management
- 2) "Return to life, return to work"

The "Return to Life, return to work" research package is a targeted research investment in stroke recovery. Two clinical trials were funded through an open and competitive process which the Stroke Foundation managed, the first for the 'Perispinal Etanercept to Improve Stroke Outcomes (PESTO) and a clinical trial led by Natasha Lannin to test the feasibility and potential benefit of building on current clinical rehabilitation by adding an embedded 12 week targeted vocational rehabilitation.

As the "Completion Date" in the current agreement is June 2021, based on their request do you think the best way is to extend the entire grant agreement to 30 December 2022? This will give them time to wrap up the project and complete the activity before then. I think the Activity Schedule will also need to be updated for this component of the project.

I will also reply to S and copy you both in and suggest that she talks to you both to work out the finer details. The GA is also attached for your info.

Happy to discuss.

**From:** S 22

**Sent:** Friday, 11 December 2020 3:41 PM

**To:** S 22

**Cc:** S 22

**Subject:** RE: PESTO trial [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

I have checked in the research team and they are actively recruiting now (super exciting). Those that are interested are asked to contact:

[pesto@florey.edu.au](mailto:pesto@florey.edu.au).

I also wanted to flag the teams involved in the Return to work, Return to life research program are set to request extensions as a result of COVID-19.

- The PESTO team will be anticipate they will need a 1 year extension – taking them to 30 June 2022.
- S 22

Let me know what you need me to do as far as next steps go. The teams are working on their reporting which from memory is next due in Jan, however I thought it made sense to flag the need now.

P

S 22

National Manager, Public Affairs & Advocacy

**Stroke Foundation**

Level 7, 461 Bourke St Melbourne VIC 3000

D 03 9918 T 03 9670 Media 0408 M 0478

7278 > 1000 > 000 409 > 199 849

StrokeLine: 1800 STROKE (1800 787 653)

S 22 [strokefoundation.org.au](http://strokefoundation.org.au)

[Email Confidentiality Statement](#)

**From:** S 22 [@health.gov.au](mailto:@health.gov.au)>  
**Sent:** Tuesday, 8 December 2020 3:26 PM  
**To:** S 22 [@strokefoundation.org.au](mailto:@strokefoundation.org.au)>  
**Cc:** S 22 [@health.gov.au](mailto:@health.gov.au)>  
**Subject:** PESTO trial [SEC=OFFICIAL]

Hi Peta,

Hope all is well.

We have received a few enquiries about the PESTO trial and I wonder if you were able to provide us with an update, if trial recruitment has commenced and if people are still able to register their interest in participating in the trial.

With thanks,

S 22

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

\f0

\f0"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged

information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission." DSP - for release under the FOIA Page 8 - FOI:300256

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w: business.gov.au  
ABN: 74 599 608 295

Program Delegate  
Medical Research Future Fund (MRFF)  
Emerging Priorities and Consumer Driven Research (EPCDR) Initiative

**For Action**

**Subject: National Stroke Foundation – CONTRACT VARIATION REQUEST**

**Timing: August 2022**

**PROPOSED ACTION**

1. That the Department of Health and Aged Care consider the proposed grant agreement variation request; and
2. If the request is approved, the Department of Health and Aged Care consider the attached draft Variation Contract and authorise the Department of Industry, Science and Resources to issue the Variation Contract to the Grantee for signature.

The proposed Agreement of Variation relates to the following grant agreement:

Program: **MRFF – Emerging Priorities and Consumer Driven Research Initiative (EPCDR)**  
Grantee: National Stroke Foundation  
Grant no: EPCD000019 (MRFF)

**Background:**

On 23 July 2018, the Department of Health and Aged Care (Health) entered into a grant agreement (the Agreement) with the National Stroke Foundation (the grantee) for an Accelerated Research (now called EPCDR Initiative) project titled; *Guidelines for Stroke Management and Return to life, return to work - recovery for young survivors*.

Grant funding of up to \$2.5million was awarded with all funds been paid in full (Attachment C). The project's original Project End Date was 30 June 2021, although on 7 June 2021 the parties varied the agreement to extend the Project End Date to 31 December 2022 (Attachment B).

The project has two distinct elements with two Activity Schedules:

Activity Schedule 1 – *'Australian Living Guidelines for Stroke Management'* (complete)

Activity Schedule 2 – *'Return to Life, Return to Work'* has two elements:

- S 22 )
- Project 2 – ‘Return to Life’ clinical trial, also called *PESTO (Perispinal Etanercept to improve Stroke Outcomes)* (delayed)

On 14 June 2022 Health conditionally approved the Grantee’s progress report for the period 1 January 2021 to 31 December 2021 with a requirement to provide an ad hoc progress report for the period 1 January 2022 to 30 June 2022. The expectation was the additional report would provide more information and a strategy moving forward regarding delays to the ‘Return to Life – PESTO’ clinical trial.

On 29 July 2022 the grantee submitted the ad hoc progress report (Attachment I) as well as a formal request to vary to agreement to extend the project end date by 12 months to enable the *PESTO* clinical trial time to achieve the outcomes as per the agreement (Attachment E).

## S 47G

### **Recommendation:**

That the Program Delegate consider this in-progress grant variation request to vary the Agreement and provide advice to BGH in relation to the following proposed option, or provide BGH with alternative guidance to action.

The Grantee has provided a clear explanation for the Covid-19 related delays and has given an assurance that the requested 12 month extension of time to the project period and revision of milestones is sufficient to allow completion of outcomes and objectives as outlined in Clause 1.3 of the Grant Opportunity Guidelines and Clauses A and B of the grant agreement.

BGH considers this variation request represents value for money and is an efficient, effective, economical and ethical use of resources that is consistent with the policies of the Commonwealth. As such, it is expected that this extension will allow the grantee to complete the agreed project milestones and outcomes as per the grant agreement.

Under Clause 8.1 in Schedule 1 of the Grant Agreement, it is recommended that Health approve the following changes (as per Attachment A - Draft Agreement of Variation) and agree to issuing the Agreement of Variation for signing by National Stroke Foundation to:

**Clause C – Duration of the Grant**

- Extend the Activity Completion Date (project end date) from 31 December 2022 to 31 December 2023
- Extend the Agreement End Date from 30 June 2023 to 30 June 2024

**Clause C – Activity Schedule – Return to Life, Return to Work**

- Amend the Activity Schedule to extend Milestone 5 from 30 April 2022 to 30 June 2023
- Amend the Activity Schedule to extend Milestone 6 from 30 April 2022 to 31 December 2023
- Amend the Activity Schedule to extend Milestone 8 from 31 December 2022 to 31 December 2023
- Amend the Activity Schedule to extend Milestone 9 from 31 December 2022 to 31 December 2023.

**Clause E – Reporting**

- Add a Progress Report for the project activity period 1 January 2022 to 31 December 2022, due 31 January 2023
- Extend the due dates for the End of Project Report and Independent Audit from 31 March 2023 to 31 March 2024.

**ST3.1 Activity Budget**

- Update the Activity Budget to incorporate actual data and revised forecast expenditure for, FY 2018-19, FY 2019-20, FY2020-21, FY2021-22, FY2022-23, FY2023-24 consistent with new information provided by the Grantee (Attachment H).

Please advise whether the proposed variation is acceptable. If so, please provide approval to issue the attached draft Variation Contract.

Alternatively, please provide additional direction. We look forward to undertaking the administration of Health's recommendation as soon as possible.

If you need any further information on the options proposed, or for any other data in relation to this issue, please feel free to contact S 22 on S 22 .

Kind regards

S 22

Program Manager  
Business Grants Hub

18 August 2022

**ATTACHMENTS**

- A: Draft Agreement of Variation
- B: Agreement of Variation Executed 2021
- C: Grant Agreement Executed 2018
- D: Grant Opportunity Guidelines
- E: Request for Variation
- F: Project Plan
- G: Risk Management Plan
- H: Budget
- I: Ad Hoc Progress Report for the period 1 January to 30 June 2022



**Australian Government**  
**Department of Health and Aged Care**

## Variation Contract

Medical Research Future Fund - Accelerated Research – neurological  
(National Stroke Foundation Inc) Grant Opportunity

EPCD000019

### Details

#### Parties

The parties to this variation contract including any schedules and annexures (“Variation”) are the parties to the grant agreement with number EPCD000019 executed on 23 July 2018 under Medical Research Future Fund Accelerated Research – neurological (National Stroke Foundation Inc) Grant Opportunity as varied from time to time (“Grant Agreement”).

#### Definition

Unless otherwise specified or the context otherwise requires, terms that are defined in the Grant Agreement have the same meaning in this Variation.

### Background

The Commonwealth and the Grantee have agreed to vary the terms of the Grant Agreement in accordance with this Variation.

### Operative clauses

1. On and with effect from the date the last party signs this Variation, the Grant Agreement is varied as set out in Schedule 1 to this Variation.
2. The parties confirm all other provisions of the Grant Agreement as previously varied as indicated at Schedule 2 and, subject only to the amendments contained in this Variation, the Grant Agreement remains in full force and effect.
3. This Variation and the Grant Agreement as previously varied as indicated at Schedule 2, when read together, contain the entire agreement of the parties with respect to the parties’ rights and obligations under the Grant Agreement.
4. This Variation may be executed in any number of counterparts. All counterparts, taken together, constitute one instrument. A party may execute this Variation by signing any counterpart.
5. In consideration of the Commonwealth entering into this Variation, the Grantee pays the sum of \$1 to the Commonwealth.
6. This Variation is governed by the laws of the Australian Capital Territory.
7. Each party will pay their own costs associated with this Variation.

For Official Use Only

## Signatures

Executed as a contract:

### Commonwealth

Signed for and on behalf of the Commonwealth of Australia as represented by the Department of Health and Aged Care by:

Name (print)	S 22
Position (print)	CEO Health and Medical Research Office S 22
Signature and date	
Witness name (print)	S 22 HEALTH AND MEDICAL RESEARCH OFFICE
Signature and date	S 22 28/10/2022

### Grantee

Signed for and on behalf of the National Stroke Foundation in accordance with section 126 of the *Corporations Act 2001* by its authorised representative:

Name of company	National Stroke Foundation ABN 42006173379
Authorised representative name (print)	S 22
Capacity of authorised representative (print)	PRESIDENT
Signature and date	S 22 24/10/2022
Witness name (print)	S 22
Signature and date	S 22 24/10/2022

For Official Use Only

## Schedule 1 - Variation to Grant Agreement

### 1. The Grant Details are varied

- Clause C, Activity Completion Date is varied by deleting 31 December 2022 and replacing it with 31 December 2023.
- Clause C, Agreement End Date is varied by deleting 30 June 2023 and replacing it with 30 June 2024.
- Clause C is varied by deleting the Activity Schedule – ‘Return to life, return to work’ and replacing it with the following Activity Schedule:

### Activity Schedules - “Return to life, return to work”.

#### A. Return to Life PESTO (Perispinal Etanercept to improve Stroke Outcomes)

No.	Title and description	Due date
1	Project start date	30 July 2018
2	Call for research applications concludes	31 December 2018
3	Successful applicant engaged	31 March 2019
4	Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30 June 2019
5	Training of staff at participating trial sites concludes	31 December 2019
6	Approved international trial sites on boarded	31 December 2020
7	Patient recruitment strategy and contingency plans - ongoing until project end	31 December 2021
8	Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31 December 2022
9	Study protocol review by Steering and Ethics Committees – as required	31 December 2022
10	Publication of study protocol and statistical analysis plan	30 June 2023
11	Patient recruitment concludes	31 December 2023

For Official Use Only

12	Clinical Trial close out, closure of sites, results written up and presented, publication plan	31 December 2023
13	Project end date	31 December 2023

S 22

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The Grant Details are varied:

- Clause E is varied by deleting the clause and replacing it with the following:

The Grantee agrees to provide the following reports to the Commonwealth representative in accordance with the reporting requirements.

Report type	Period start date	Period end date	Agreed evidence	Due date
Progress report	Project start date	31 December 2018	Progress report	31 January 2019
Progress report	1 January 2019	31 December 2019	Progress report	31 January 2020
Progress report and risk management plan	1 January 2020	30 June 2020	Progress report	31 July 2020
Progress report	1 July 2020	31 December 2020	Progress report	31 January 2021
Progress report	1 January 2021	31 December 2021	Progress report	31 January 2022
Ad Hoc report	1 January 2022	30 June 2022	Ad Hoc report	31 July 2022
Progress report	1 January 2022	31 December 2022	Progress report	31 January 2023
End of project report	Project start date	31 December 2023	Satisfactory completion of an end of project report	31 March 2024
Independent audit report	Project start date	31 December 2023	Satisfactory report completed by independent auditor	31 March 2024

During the Agreement period, the Commonwealth may ask the Grantee for ad-hoc reports on the project. The Grantee must provide these reports in the timeframes notified by the Commonwealth.

For Official Use Only

2. The Supplementary Terms are varied:

- Subclause ST2.2 is varied by deleting the subclause and replacing it with the following:

The Grantee agrees to use the Grant and any Other Contributions and undertake the Activity consistently with the Activity Budget in the following table:

S 47G

Total	S 47G	\$2,500,000*
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Figures in the above table are GST inclusive amounts less GST credits that can be claimed in relation to the expenditure.

For Official Use Only

## Schedule 2 – Previous amendments to the Grant Agreement

The Grant Agreement has been previously amended as set out below:

- Deed of variation executed on 7 June 2021 to extend the Activity Completion Date from 30 June 2021 to 31 December 2022.

# Progress Report

## Accelerated Research program

Submit your completed report to [arp@industry.gov.au](mailto:arp@industry.gov.au)

Grantee name	National Stroke Foundation
Project title	S 22 2. "Return to life, return to work" stroke recovery for young survivors
Project number	MRFF-N-SF
Reporting period	30 July 2018 to 31 December 2018

### 1. Project progress

- a. Complete the following table, updating for all milestones shown in the Activity Schedule of your grant agreement. Add rows as required.

#### 1. Australian Living Guidelines for Stroke Management

No	Milestone description	Agreed completion date	Actual /anticipated completion date	Milestone progress (% complete) at end of reporting period
	<b>Milestone 1</b> Start date	30 July 2018		
	<b>Milestone 2</b> Project Evaluation – create evaluation plan	30 September 2018		
	<b>Milestone 3</b> Establish platform and methods – design and build	31 December 2018		

2. "Return to life, return to work" stroke recovery for young survivors

No	Milestone description	Agreed completion date	Actual /anticipated completion date	Milestone progress (% complete) at end of reporting period
	<b>Milestone 1</b> Project start date	30 July 2018		
	<b>Milestone 2</b> Call for research applications concludes	31 December 2018		

b. Describe the eligible activities you completed during this reporting period, including your progress against milestones and any outcomes achieved. If applicable, comment on why your progress is delayed.

[Empty text box for response to question b]

c. Attach evidence to demonstrate your progress against project milestones this reporting to date. List the attached documents below against the relevant activity/s, or provide web links for any publicly available information.

[Empty text box for response to question c]

d. Is the overall project proceeding in line with your project plan and grant agreement?  yes  no

If no, identify any changes or anticipated issues. Comment on any impacts on project timing and outcomes and how you expect to manage these.

[Empty text box for response to question d]

e. Are there any planned events relating to the project that you are required to notify us about in accordance with your agreement?  yes  no

If yes, please provide details of the event including date, time, purpose of the event and key stakeholders expected to attend.

[Empty text box for response to question e]

2. Eligible expenditure summary

a. Complete the following table to show:

- i. total eligible expenditure incurred on the project prior to this reporting period
- ii. eligible expenditure incurred in this reporting period

iii. estimated eligible expenditure for the remainder of the project.

If you are registered for GST, enter GST exclusive figures. If you are not registered for GST, enter GST inclusive figures. We may ask you to provide evidence of costs incurred.

Refer to the Accelerated Research grant opportunity guidelines or contact us if you have any questions about eligible expenditure.

Eligible project expenditure	Total
i. Eligible expenditure incurred prior to this reporting period	\$
i. Eligible expenditure incurred this reporting period	\$
ii. Estimated expenditure for next reporting period	\$
iii. Estimate for remaining reporting periods in current financial year (if applicable)	\$
iv. Estimated total expenditure in [20xx-xx]	\$
v. Estimated total expenditure in [20xx-xx]	\$
vi. Estimated total expenditure in [20xx-xx]	\$
vii. Total estimate for project	\$

b. Briefly explain the reason for any changes between the forecast and actual expenditure for the current reporting period, and any significant changes to the forecast budget for the remainder of the project.

c. Is the project expenditure broadly in line with the activity budget in the  yes  no grant agreement?

If no, explain the reasons.

### 3. Bank account details

Have your bank account details changed since your last payment?  yes  no

If yes, we will provide you with a form to complete your new bank details.

### 4. Certification

I .....being a person duly authorised by the grantee hereby certify that:

- the information in this report is accurate, complete and not misleading and that I understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- the activities identified above are for the purposes stated in the grant agreement.

- I am aware of the grantee’s obligations under their grant agreement, including the need to keep the Commonwealth informed of any circumstances that may impact on the objectives, completion and/or outcomes of the agreed project.
- I am aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

Signed ..... Date

[Position/ title]



















## Medical Research Future Fund – Accelerated Research Progress Report Assessment

Project number	MRFF-N-SF (ARG73055)
Grantee	National Stroke Foundation
Project title	S 22 2. “Return to life, return to work” stroke recovery for young survivors
Grant Activity	Neurological
Reporting period	30/7/18 to 31/12/18
Project risk rating*	Low

### Notes:

This assessment report has a number of purposes which include but are not limited to:

- Providing a basis for making payments
- A record of the review of progress against a grant agreement
- To inform stakeholders on key aspects of the program
- Recordkeeping/AusIndustry due diligence

Information contained in this assessment report, together with the project progress report, may be used in stakeholder reports by the Department of Industry, Innovation and Science and the Department of Health.

All financial information contained within this assessment report, including the grant amount, is GST exclusive.

As per the Ad Hoc Grant Opportunity Service Schedule, default project risk rating is low.

## Accelerated Research Program - Progress report assessment

### 1. Milestones and Project Progress

1.1	Are the activities and milestones in the project report progressing according to the grant agreement?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>This project has two distinct subprojects, both of which are progressing well against the agreed milestones: s22</p> <ul style="list-style-type: none"> <li>• <b>‘Return to life, return to work’ stroke recovery for young survivors -</b> The Stoke Foundation Research Advisory Committee is currently assessing 12 proposals from organisations around the world based around research question ‘How can return to work rates be improved for younger stroke survivors in Australia?’ The committee will meet on 22 February 2019 to make recommendations for funding to top ranked proposals. Milestones 1 and 2 are both 100% complete.</li> </ul>		

### 2. Project Plan

2.1	Are there any developments that may impact on the future success or timing of the project?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>s22</p> <ul style="list-style-type: none"> <li>• <b>“Return to life, return to work” stroke recovery for young survivors –</b> the project is currently meeting the milestone deadlines, however, a delay in opening for applications (due to a delay in Ministerial announcement of the grant) may have an impact Milestone 4, due 30 June 2019. The grantee indicates that it has made research teams aware of the project timings, and will be working towards meeting milestone.</li> </ul>		
2.2	Has the grantee advised of any planned events relating to this project?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>The grantee has reported: <i>The Australian Government can choose to announce individual grant recipients at its discretion in partnership with Stroke Foundation and the successful researcher institutions.</i> Based on this information, there is no specific events planned.</p>		

### 3. Evidence of expenditure

3.1	Does the report indicate that there is reason to request payment records of eligible expenditure?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p><i>If required, please provide comment:</i></p>		

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**4. Eligible expenditure for the reporting period**

4.1	What is the total eligible expenditure for the reporting period?	S 47G (excl GST)
4.2	Are there any significant changes between the forecast and actual expenditure of the current reporting period?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4.3	Are there any significant changes to the forecast budget for the remainder of the project?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p><i>If required, please provide comment:</i></p> <p>Although there is a lag between milestone completion and claiming associated expenditure, the report does indicate that the next reporting cycle is expected to see expenditure quadruple, which aligns with the payment schedule.</p>		

**5. Bank Details**

5.1	Has the grantee's bank account details changed?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
5.2	If yes, have the grantee been provided with a supplier form?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

**6. Certification**

6.1	Has the report been certified?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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**7. Special conditions**

7.1	Do any Special Conditions apply to this grant?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
-----	--	---

**8. Risk rating**

8.1	Based on the progress report, what is the project risk rating?	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Medium <input type="checkbox"/> High
<p><i>If medium or high risk, what strategies have been implemented to move the risk rating to an acceptable low risk level?</i></p> <p>Based on the information provided in the report, the project risk is rated low.</p>		

**9. Payment recommendation**

9.1	Is the payment recommended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
S 47G		

**Report Review**

**I have undertaken the assessment of the Accelerated Research Program recipient’s progress report**

CSM name:	s22
Date:	15 February 2019

**I have verified the review of the Accelerated Research Program recipient’s progress report**

Authorised Officer name:	s22
Date:	18 February 2019

# Application EPCD000019

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## Report Summary

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**Report**

EPCD Progress Report 3

**Report Type**

Progress

**Due Date**

30/01/2021 12:00:00 AM

**Status**

Accepted

**Submitted Date**

29/01/2021 4:29:05 PM

**Submitted By**

s22

**Report Accepted Date**

1/02/2021 12:00:20 AM

## Project progress

---

Complete the following table, updating all milestones shown in your grant agreement. The expected end date is generally the milestone end date in your grant agreement. You should update this if your milestone timing has changed.

### Milestones

---

s22

s22

1

s22

s22

**004 - Call for research applications concludes - Return to life**

**Description**

**Expected End Date**

30/12/2018

**Actual End Date**

30/11/2019

**Current % Complete**

100

**Progress Comments**

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

s22

**006 - Trial endorsement - Return to life, return to work****Description**

Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration.

**Expected End Date**

30/06/2019

**Actual End Date**

28/06/2019

**Current % Complete**

100

**Progress Comments**

PESTO ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration 22/09/2020. RTW trial registration 20/08/2019; ethics 2/09/2019; ASTN 06/11/2019

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

s22

**008 - Staff training concludes - Return to life, return to work**

---

**Description**

Training of staff at trial sites concludes

**Expected End Date**

31/12/2019

**Actual End Date**

27/10/2020

**Current % Complete**

100

**Progress Comments**

PESTO - Austin Health-27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) -17/12/2020 & 14&18-01/2021. Pending Alfred Health and Nottingham University (UK). RTW - 30/11/2019

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

s22

**010 - Publication of protocol & plan - Return to life, return to work**

---

**Description**

Publication of study protocol and statistical analysis plan

**Expected End Date**

31/12/2020

**Actual End Date**

60

**Current % Complete**

60

**Progress Comments**

PESTO - To be performed at conclusion of recruitment. RTW - Draft completed and circulated to co-authors. Leave and transition of team members following academic changes delayed milestone (coronavirus pandemic (COVID-19) related)

**Agreed End Date**  
30/06/2021

**Previous % Complete**  
0

s22

**012 - Patient recruitment concludes**

---

**Description**  
Patient recruitment concludes

**Expected End Date**  
31/12/2020

**Actual End Date**

**Current % Complete**  
15

**Progress Comments**  
PESTO - 5 patients enrolled in 2020 (Nov-Dec). s22

**Agreed End Date**  
30/06/2021

**Previous % Complete**  
0

s22

s22

### 014 - Finalise Data Safety & Monitoring committee

---

**Description**

Establishment of Data Safety and Monitoring Committee and its Charter is finalised.

**Expected End Date**

30/06/2021

**Actual End Date**

**Current % Complete**

60

**Progress Comments**

PESTO - DSMC established 15/10/2019. To be done once all data is analysed and trial close out ready s22

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

s22

s22

**016 - Clinical trial close out - Return to life, return to work**

---

**Description**

Clinical trial close out, closure of sites, results written up and presented, publication plan

**Expected End Date**

30/06/2021

**Actual End Date****Current % Complete**

34

**Progress Comments**

PESTO - Request extension of 12 months due to COVID impact in 2020. To be done once all data is analysed and trial close out ready.

s22

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

s22

**018 - Project end date - Return to life, return to work**

---

**Description**

Project completed

**Expected End Date**

30/06/2021

**Actual End Date****Current % Complete**

34

**Progress Comments**

PESTO - request extended end date - 30/06/2022. RTW - request extended end date - 31/12/2021

7

**Agreed End Date**

30/06/2021

**Previous % Complete**

0

Where applicable, describe any project activities completed during the reporting period that are not captured in the table above.

s22

Return to life, return to work

PESTO - The Coronavirus pandemic had direct and indirect impact on the project in 2020. As a result, a 12 month extension has been requested. The greatest impact has been on recruitment, which was due to start in March 2020 following Austin Health Research Governance Office (RGO) approval. COVID-19 meant recruitment was paused between March (refer Attachment 2) and October 2020. During this period, potential participants were able to complete an online feasibility questionnaire to determine their eligibility to participate in the next stage of screening required by the trial protocol. During the pause in recruitment, during COVID-19 restrictions, the project continued to remain in contact with interested participants via PESTO mailbox and keep them updated on current satiation with the trial and engaging with them via email updates. Actions taken to ensure recruitment is addressed include i) onboarding of an additional site in New Zealand (NZ), as Coronavirus pandemic cases were more under control as compared to the rest of the world, as well as their Ethics review/approval process turnaround time is efficient and by adding another site, we are targeting to boost recruitment ii) increased promotion for participants following ethics approval for the advertising material (from early 2021), iii) re-contact with interstate participants interested in the trial, as border closures have/begin to ease in Australia. Active recruitment has recommenced since COVID restrictions were eased in November, with the first patient screened on 6 November 2020. Five patients were enrolled onto the PESTO trial in 2020 (Nov-Dec 2020).

s22

**Is the overall project proceeding in line with your grant agreement?**

No

**Identify any changes or anticipated issues.**

**Comment on any impacts on project timing and outcomes and how you expect to manage these.**

ALGSM - This project is proceeding in line with the grant agreement.

Return to life, return to work

PESTO - A 12 month extension is requested. As reported in January 2020, initial recruitment was anticipated to conclude 31 December 2021. Revised timelines were submitted to Stroke Foundation per Research Grant Variation Form to 30 April 2022 due to the impact of COVID-19 pandemic. There is a possibility the recruitment timelines may need to be extended, but with two other sites soon to begin recruiting (CGM Research Trust and Alfred Health) in 2021, a clearer picture of how recruitment will progress will be known by end March 2021. The UK site is yet to submit to Ethics and may experience further delays due to the impact of COVID-19 lockdowns. Currently the project is counting on three sites to actively recruit. Work continued during the COVID-19 lockdown such as Case Report Form (CRF)/database set-up, creation of source documents/tools, set-up of sites, adding on additional (NZ) site (involving Ethics and Locality/Maori Approvals, contract and site budget negotiation), hosting and managing monthly steering committee meetings.

Every effort is being made to carry out the project under the revised timelines and same budget. However, with extended recruitment timelines and overall extension of project timeline deliverables, there are factors involved which affect the budget. Extending the trial impacts budget items that need to be covered for the timeline extension such as any annual fees paid to the site (pharmacy, laboratory) as well as Project coordinator & monitoring PSP4 (as per grant application). S 47G . We will work with the research team to finalise the anticipated financial impact of the delays associated with COVID-19 and confirm these with the Department. We will assess options for sourcing the additional research funding required to complete the project as per the original scope. We will also explore with the research team if there are any options to reduce the scope of the project if additional funding cannot be secured.

s22

s22

**Are there any planned events relating to the project that you are required to notify us about in accordance with your agreement?**

No

**Provide details of any publications, media articles, presentations, conference abstracts, or other instances where your funded research was shared, promoted, or otherwise disseminated. Please also include the number (if any) of patents filed as a result of research funded through this program and detail any potential or established spin-offs or collaborations which have arisen as a result of this research.**

s22

PESTO - Trial recruitment advertising approved by the Ethics committee is being utilised, the Investigators spreading awareness at respective hospitals and among peers.

s22

**Have you complied with all legislation applicable to the delivery of the activity as outlined in ST20 of this Agreement?**

Yes

## Project outcomes

---

**Outline the project outcomes achieved to date.**

**As per the objectives in Section 1.3 of the Grant Opportunity Guidelines.**

s22

Return to life, return to work

PESTO - The first and lead site (Austin Health) is initiated and has commenced screening and recruitment of trial participants. Austin Health have enrolled five participants and will continue to recruit in 2021. Two further sites (CGM Research Trust and Alfred Health) are in the final stages of Ethics/Research Governance Office and Locality/Maori Approvals (NZ) and will be initiated in early 2021 and begin recruitment.

s22

**Outline the extent to which you have met the project objectives to date**

**As per the Section 1.3 of the Grant Opportunity Guidelines.**

s22

s22

Return to life, return to work

PESTO - As COVID-19 restrictions have eased in Australia, promoting trial recruitment is a priority for 2021 per revised timelines. Recruitment is active and The Florey Institute of Neuroscience & Mental Health communications team will promote/advertise the PESTO trial on their online platform. The Investigator team has continued to onboard other sites. The project is tracking to deliver agreed outcomes, subject to the extended timeframe. Due to the directed and indirect impact of the COVID-19 pandemic the decision was made to increase the number of participating sites from three to four (the fourth site being in New Zealand). The four sites are as follows; 01 Austin Health, 02 Alfred Health, 03 University of Nottingham, 04 Canterbury Geriatric Medical (CGM) Research Trust. Site 01 have Ethics/RGO approval 2020; Site 02 have Ethics approval, RGO in review; Site 03 are yet to submit to their Ethics, as there has been some changes and priority due to COVID-19 studies, as well as pending further funding from other sources to run the trial so are targeted to submit to their ethics in early 2021; Site 04 have Ethics/local approval January 2021. By adding the fourth site (04 CGM Research Trust), the project is targeting to help boost recruitment, thus project outcomes and objectives.

s22

#### Are you on track to deliver these project outcomes and objectives?

No

#### Provide information about your progress against your project milestones:

- Describe the extent to which your progress supports your achievement of key project activities.

s22

Return to life, return to work

PESTO -

1. Austin Health actively recruiting patients.
2. Online feasibility questionnaire set-up in Feb-2020 to pre-screen interested participants
3. Site Initiation Visit (SIV) presentation, tools (source documents), manuals (pharmacy, IP administration) developed and trained to sites via Zoom.
4. SIV conducted for CGM Research Trust (NZ site) in Jan-2021. Site to begin recruitment.
5. Alfred Health - RGO comments received Jan-2021, soon to achieve approval and perform SIV and begin recruitment.

s22

#### What is the most important finding from your research to date?

- Have you found new and/or unexpected findings or outcomes through the process?

s22

Return to life, return to work

PESTO - There is a community appetite for the trial's results and advancements in the area of stroke recovery. There has been significant community interest in the project. Interested participants have remained engaged with the trial throughout 2020 via a variety of communications mediums in spite of the pandemic.

s22

#### What is your strategy for disseminating that knowledge and supporting its path to full implementation?

- Have you identified enablers and/or barriers to the translation/implementation of your research findings?

s22

Return to life, return to work

PESTO -Austin Health site has been active in recruiting all PESTO trial patients to date, and leads the pre-SIV Zoom calls between other sites that are ready/close to be initiated (SIV) with the Sponsor to allow Professor Vincent Thijs (also Austin Principal Investigator) and Florey Project Manager to share lessons learned as well as best practices that could aid the site with onboarding, operations, as well as recruitment. Site discussions, challenges, recruitment will continue to be discussed during monthly steering committee meetings, where all Site Principal Investigators are present.

s22

## Project expenditure

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Provide the following information about your eligible project expenditure.

All expenditure should be GST inclusive, less GST credits you can claim. We may ask you to provide evidence of costs incurred.

Refer to the grant opportunity guidelines or contact us if you have any questions about eligible expenditure.

**ReportStartDate**

1/01/2020

**ReportEndDate**

31/12/2020

S 47G

### Comments

The financial data entered into Section 4: Project expenditure is provided within the available fields for input. Please note that the reporting for this period has been calculated by financial years as indicated by the template. Our previous financial report submitted in January 2020 was calculated in accordance with the Department's advice and the Stroke Foundation's financial year ending 31 December. The column 'Expenditure approved prior to this reporting period' is disabled in the portal. Our portal figures have been provided in order to overcome a system error related to 'Expenditure claimed to date' totals in the portal. Therefore we have entered both prior expenditure and expenditure claimed in this period in the same column ('Expenditure claimed in this reporting period') to ensure the total project expenditure is reflected. We provide an attachment of this period's financial acquittal as per the Section 4: Project Expenditure template and our financial records in all relevant fields. (Refer advice provided by Daniel Baer, National Outreach and External Grants Administration, Victoria State Office, AusIndustry - Support for Business 27/01/2021 and 29/01/2021.)

### **Briefly explain the reason for any changes between the forecast and actual expenditure for the current reporting period, and any significant changes to the forecast budget for the remainder of the project.**

During this reporting period, the second instalment of funds for the PESTO trial was withheld due to the trial paused between March and October 2020 in accordance with COVID restrictions (refer Attachment 2 and Section 2: Project progress). The PESTO trial has recommenced recruitment since November 2020 and the next instalment of funds will occur in the next reporting period (2021).

### **Is the project expenditure broadly in line with the activity budget in the grant agreement?**

Yes

## Bank account details

---

### **Have your bank account details changed since your last payment or since you last provided them?**

**If yes, we will provide you with a form to complete your new bank account details.**

**If you are not due any further payments, select not applicable.**

No

## Attachments

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## Additional documents

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### Additional supporting information

If you need to provide additional documents such as copies of published reports etc related to the project, you should attach them here.

2020 Att 1. MQ LSG evaluation.pdf

2020 Att 2 PESTO Trial\_COVID-19\_update\_letter\_19Mar2020.pdf

2020 Att 3. Alfred Health Contingency Plan for COVID19 Interruption to Clinical Trials 13-Mar-2020.pdf

2021-01 MRFF Progress Report 3\_Section 4 Project Expenditure Table.pdf

## Declaration

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### Report Declaration

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I am authorised by the grantee to submit this report and certify that:

- the information in this report is accurate, complete and not misleading and that I understand the giving of false or misleading information is a serious offence under the *Criminal Code Act 1995* (Cth)
- the activities undertaken and the expenditure incurred is in accordance with the grant agreement
- I am aware of the grantee's obligations under their grant agreement
- I am aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

**By checking this box I agree to all of the above declarations and confirm all of the above statements to be true**

Yes



## Medical Research Future Fund – Emerging Priorities and Consumer Driver Research (formerly Accelerated Research Initiative)

### Progress Report Assessment

<b>Grantee Name</b>	National Stroke Foundation
<b>Project title</b>	S 22 2. "Return to life, return to work" stroke recovery for young survivors
<b>Project number</b>	EPCD000019
<b>Reporting period</b>	01/01/20 – 31/12/20
<b>Related payment</b>	S 47G
<b>Project risk rating*</b>	Low

#### Notes:

This assessment report has a number of purposes which include but are not limited to:

- Providing a basis for making payments
- A record of the review of progress against a grant agreement
- To inform stakeholders on key aspects of the program
- Recordkeeping/AusIndustry due diligence

Information contained in this assessment report, together with the project progress report, may be used in stakeholder reports by the Department of Industry, Science, Energy and Resources and the Department of Health.

All financial information contained within this assessment report, including the grant amount, is GST exclusive.

As per the Ad Hoc Grant Opportunity Service Schedule, default project risk rating is low.

## EPCDR/AR - Progress report assessment

### 1. Project Progress

1.1 S 22	Are the milestones progressing according to the project plan and grant agreement?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>The second of the subprojects is called '<b>Return to life, return to work</b>' stroke recovery for young survivors. This subproject is about facilitating clinical research activity and promoting greater access to innovative and cutting edge treatments for stroke survivors of working age. While there has been significant progress made the pandemic has adversely impacted and delayed activities directly and indirectly, reducing, for example, the recruitment of patients. Note also the grantee has reported the milestone progress for this sub-project in two parts, specifically:</p> <ul style="list-style-type: none"> <li>○ PSE: Perispinal Etanercept to improve Stroke Outcomes (PESTO)</li> <li>○ RTW: Early vocational intervention for people who have experienced stroke: A randomised pilot trial</li> </ul> <p><b>Pesto Milestones progress:</b></p> <p>Publication of study protocol and statistical analysis plan: to be concluded once patients recruitment has been finalised. This was due by 31/12/2020 with 5 patients enrolled in 2020 (Nov-Dec). However due to Covid-19, it appears to have been delayed by 12 months. However, as the delegate has agreed to extend the Activity Completion Date (project end date) to 31/12/2022 risks arising from delay have largely been mitigated (Agreement of Variation executed on XX June 2021).</p>		

S 22

1.2 S 22	Has the grantee completed any additional project activities in addition to those in the milestone table?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>S 22</p>		

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S 22

PESTO:

PESTO inbox set up for recruitment and engagement during lockdown periods of the Covid-19 pandemic. New Zealand site established as covid-19 cases were under control and recruitment could be generated at this site.

S 22

<b>1.3</b>	<b>Has the grantee notified of any planned events in relation to the project?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
------------	---	---

No planned events to take place at this stage.

<b>1.4</b>	<b>Has the grantee complied with all legislation applicable to the delivery of the activity as outlined in their agreement? If not, please provide an explanation why.</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
------------	--	---

Yes, the Grantee has reported they are complying with all of the legislation as outlined in the agreement.

## 2. Project Outcomes

<b>2.1</b>	<b>Is the project meeting the project outcomes and objectives?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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S 22

PESTO - As COVID-19 restrictions have eased in Australia, promoting trial recruitment is a priority for 2021 per revised timelines. Recruitment is active and The Florey Institute of Neuroscience & Mental Health communications team will promote/advertise the PESTO trial on their online platform. The Investigator team has continued to on board other sites.

S 22

<b>2.2</b>	<b>Have there been, or are there expected to be, any issues delivering the project objectives and outcomes?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	<b>Is project delivery on track?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Grantee initially highlighted in February 2020 that an extension of 12 months to project end date may be required. It is now clear that the inability to recruit patients for the trials due to Covid-19 has caused some aspects of the project to be delayed. S 22

<b>2.3</b>	<b>Has information been provided about project milestones supporting achievement of key project activities?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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S 22

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PESTO – patient recruitment has occurred with Austin Health. Feasibility questionnaire has been set up to pre-screen participants. S 22		
2.3	What is the most important finding from the research to date? Have there been any new or unexpected findings/outcomes?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
S 22  PESTO - There is a community appetite for the trial's results and advancements in the area of stroke recovery. There has been significant community interest in the project.		
2.4	How has the information been disseminated? Have any enablers and /or barriers been identified?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
S 22  PESTO: Site discussions, sharing lessons learnt, challenges, and recruitment are being discussed during monthly steering committee meetings, where all Site Principal Investigators are present. S 22		

### 3. Project Expenditure

3.1	Does the report indicate that eligible expenditure is broadly in line with the activity budget in the grant agreement?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Expenditure appears to be in line with the activity budget within the grant agreement. There have been some reductions in domestic travel associated with Covid-19 restrictions.		
3.2	What is the total eligible expenditure for the reporting period?	S 47G (excl GST)
3.3	Are there any significant changes to the forecast budget for the remainder of the project?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>To date, the Grantee claims it has incurred S 47G</p> <p>For reference the original Agreement estimated that by 30 June 2020 \$1.8m would be spent and that all funding (\$2.5m) would be spent by 30 June 2021.</p> <p>Note also the grantee initially reported some concerns in regard to an overspend (funding shortfall) but in the course of liaising with BGH updated their position noting the issue has been resolved. A review of the project budget has found that the actual patient costs are around S 47G Therefore around S 47G is available and will cover any costs associated with the extension of the project if approved (i.e.the projected shortfall is no longer an issue if the project is extended).</p> <p>The project scope and activities under PESTO remains on target with patient recruitment numbers to remain as per original number of 168.</p> <p>The project scope and activities for RTW patients' numbers is likely to reduce from the original of 54 to 30 if the extension is granted. However, the Grantee is confident that even with the reduced numbers of patients, the project overall will achieve the desired results.</p>		

### 4. Attachments

4.1	Has the grantee attached any agreed evidence required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
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*sites are similar to Australians and results may be able to be extrapolated to Australian populations. Please continue to explain and highlight these benefits to Australians in your grant reporting.”*

**7. Payment recommendation**

7.1	Based on the progress reporting, is the payment recommended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
S 47G		

**Report Review**

**I have undertaken the assessment of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient’s progress report**

CSM name:	S 22
Date:	08 June 2021

**I have verified the review of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient’s progress report**

Authorised Officer name:	S 22
Date:	8 June 2021



## Medical Research Future Fund – Accelerated Research Initiative Progress Report Assessment

<b>Grantee Name</b>	National Stroke Foundation
<b>Project title</b>	S 22 2. "Return to life, return to work" stroke recovery for young survivors
<b>Project number</b>	ARG73055 (MRFF-SF)
<b>Reporting period</b>	01/01/2019 to 31/12/2019
<b>Project risk rating*</b>	Low

### Notes:

This assessment report has a number of purposes which include but are not limited to:

- Providing a basis for making payments
- A record of the review of progress against a grant agreement
- To inform stakeholders on key aspects of the program
- Recordkeeping/AusIndustry due diligence

Information contained in this assessment report, together with the project progress report, may be used in stakeholder reports by the Department of Industry, Innovation and Science and the Department of Health.

All financial information contained within this assessment report, including the grant amount, is GST exclusive.

As per the Ad Hoc Grant Opportunity Service Schedule, default project risk rating is low.

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## EPCDR/AR - Progress report assessment

### 1. Project Progress

1.1	<b>Are the activities and milestones progressing according to the project plan and grant agreement?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p>This project has two distinct subprojects: S 22</p> <ul style="list-style-type: none"> <li>• <b>'Return to life, return to work' stroke recovery for young survivors -</b> Facilitating clinical research activity and promote greater access to innovative and cutting edge treatments for stroke survivors of working age. Milestones 1, 2 &amp; 3 are 100% complete, subsequent milestones are at various stages of completion ranging from 0% – 50%. Issues have been identified as further discussed below. The grantee reports that the issues reported will have an impact on the project completion date for the second sub-project. The grantee has reported the milestone progress for this sub-project in two parts, these are: <ul style="list-style-type: none"> <li>○ PSE: Perispinal Etanercept to improve Stroke Outcomes (PESTO)</li> <li>○ S 22</li> </ul> </li> </ul> <p>For the purposes of assessing this report, this sub-project has been assessed as one item and time frames are discussed as both parts combined.</p>		
1.2	<b>Has the grantee notified of any planned events in relation to the project?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

### 2. Project Outcomes

2.1	<b>Is the project meeting the project objectives and outcomes?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>The project has faced delays but appears to be on track to deliver the agreed project objectives and outcomes.</p>		
2.2	<b>Have there been, or are there expected to be, any issues delivering the project objectives and outcomes?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p><i>Living Guidelines;</i> This sub-project looks to be on track. <i>Return to Life, Return To Work;</i> The grantee reports that issues delaying the project at the beginning have been addressed and that trials are expected to commence recruitment early February 2020. The issues reported related to:</p> <ul style="list-style-type: none"> <li>• Austin Research Governance Office approval (submitted on 24 September 2019)</li> <li>• Discussions with the Dr Edward Tobinick who is the holder of the treatment patent, regarding injection training and the patent</li> </ul> <p>• S 42</p>		

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- Recruitment delays due to a high number of ineligible patients screened, the primary reason cited is due to concurrent enrolment in another clinical trial.

Although the grantee has reported that these issues have been addressed and that they should be able to catch-up, they have requested to extend the final 2 milestone and project end date completion dates by 12 months to the 30<sup>th</sup> June 2022.

AusIndustry has discussed the variation process with the grantee, and recommends delaying a variation until the end of the 2020 reporting period to incorporate any unforeseen issues, or progress made against milestones, this year.

<b>2.3</b>	<b>Have there been any new or unexpected findings/outcomes from the research to date?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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*Living Guidelines;*

No preliminary findings reported at this early reporting stage.

*Return To Life, Return To Work;*

No preliminary findings reported at this early reporting stage.

### 3. Expenditure

<b>3.1</b>	<b>Does the report indicate that eligible expenditure is broadly in line with the activity budget in the grant agreement?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
The grantee has advised that expenditure is broadly in line with the activity budget.		
<b>3.2</b>	<b>What is the total eligible expenditure for the reporting period?</b>	<b>S 47G (excl GST)</b>
<b>3.3</b>	<b>Are there any significant changes to the forecast budget for the remainder of the project?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
The forecasted project budget is reported to be on track.		

### 4. Attachments

<b>4.1</b>	<b>Has the grantee attached any agreed evidence required?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>4.2</b>	<b>Has the grantee attached any published reports or promotional material?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
<p>The grantee has provided the following listed attachments (see Evidence of Activity doc):</p> <ol style="list-style-type: none"> <li>Letter confirming NHMRC CEO approval of the amended recommendations in the Clinical guidelines for stroke management.</li> <li>Stroke Foundation Media Release - Return to Life, Return to Work research grants announced.</li> <li>Letter confirming ASTN endorsement of the PESTO trial.</li> <li>Austin Health HREC approval of the PESTO trial.</li> <li>Austin Health HREC approved Participant Information Sheet/Consent Form for the PESTO trial (Master)</li> <li>Austin Health HREC approved Person Responsible Information Sheet/Consent Form for the PESTO trial.</li> <li>Alfred Hospital HREC approval for the Return to Work trial.</li> <li>Letter confirming ASTN endorsement of the Return to Work trial.</li> <li>Alfred Health approved Participant Information Sheet for the Return to Work trial.</li> <li>Knowledge Dissemination and Transition Plan for the Return to Work trial.</li> <li>S 47G</li> <li>Return to Work trial registration</li> </ol>		

### 5. Certification

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5.1	Has the report been certified?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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**6. Risk rating**

6.1	Based on the progress report, what is the project risk rating?	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
<p><i>If medium or high risk, what strategies have been implemented to move the risk rating to an acceptable low risk level?</i></p> <p>Medium – the risk rating for this report is medium due to delays facing the project.</p> <p>The grantee has indicated that a 1 year extension may be required to the project end date (to 30 June 2022) due to the issues discussed in 2.2.</p> <p>AusIndustry recommends assessing the progress reporting due in January 2021 for further progress against milestones. If required, a formal variation can then be processed along with the January 2021 reporting.</p>		

**7. Payment recommendation**

7.1	Based on the progress reporting, is the payment recommended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Based on the progress against milestones, it is recommended that the progress payment of S 47G		

**Report Review**

**I have undertaken the assessment of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient's progress report**

CSM name:	S 22
Date:	17/02/2020

**I have verified the review of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient's progress report**

Authorised Officer name:	S 22
Date:	19/02/2020



12 May 2021

S 22

Program Management and Delivery  
Business Grants Hub  
Department of Industry, Science, Energy and Resources

*Sent via email:* arp@industry.gov.au

Dear S 22

**RE: MRFF-N-SF A17.04 Accelerated Research Program: ‘Return to life, return to work’**

I refer to the meeting on Monday 3 May 2021 seeking clarification of eligible expenses specifically for the PESTO trial international sites and in consideration of the ‘Return to life, return to work’ clinical trials extension request. Thank you for the opportunity to provide supplementary information, which we outline as follows:

**1. Context and importance of international sites for the PESTO clinical trial funded by the MRFF.**

**Context of PESTO trial and trial design**

PESTO is a phase 2b, international, investigator initiated, multicentre, prospective, randomised, sham-controlled efficacy trial.

Designed from the outset as an international trial to address the current application of etanercept to ensure generalisability and counter claims of selection bias, this trial needed to test the treatment in a broad sample of stroke survivors. In selecting primary and secondary outcomes the research team considered the recommendations of an international group of leading experts in stroke recovery.

The scoring matrix used by peer reviewers in assessing the proposal referenced international standards and scope/reach.

**Selection of sites**

The COVID-19 pandemic has rendered significant challenges and disruption to the clinical trial and sites onboarding including but not limited to:

- Sufficient access and budget for site costs and training of investigators able to do the procedure.
- Increased length of processing time for ethics and site governance approvals as a direct impact of COVID-19.

- Consideration of restrictions and uncertainty for research activity and interstate travel within Australia.

This study has selected Australian, UK and more recently NZ study centres experienced in stroke recovery trials, as an optimum strategy to achieve the planned outcomes for the project, including the required number of participants enrolled in the trial. The NZ site is the most recent site added as a mitigation strategy to ensure the project can achieve the target number of participants given the ongoing COVID19 related restrictions in the UK.

The study has a strong executive committee of national and international stroke, clinical trial design and stroke recovery leaders, experienced in the formulation, conduct and analysis of clinical trials leading to high quality publications.

The revised recruitment strategy/targets to reach the sample size (n=168) across PESTO sites to achieve the planned outcomes of the project are:

- Target recruitment for Australian sites = 60% (n=98)
- NZ site = 30% (n=50)
- UK site = 10% (n=20)

S 47G

### **International significance of outcomes of PESTO trial**

If a positive effect is confirmed, larger trials may need to be performed to assess safety and efficacy of further, repeated administration. If the trial does not achieve the primary endpoint, research should focus on other ways to improve outcomes after disabling stroke. This trial will inform the public and health care providers whether this treatment should be recommended to improve patient reported outcomes. This will be of major importance to the large, world-wide community of stroke survivors.

#### **2. Expenditure for patient recruitment and participation in the international sites for the PESTO trial in line with 'eligible expenditure' as defined under the Grant Agreement.**

It is in our view that the expenses incurred are consistent with and meet the definition of 'eligible expenditure' of the Grant, having met the following conditions:

1. There is no express prohibition in the Agreement or the grant opportunity Guidelines regarding the recruitment and participation at international trial sites.

2. The expenditure associated with patient recruitment and participation meet the criteria of 'eligible expenditure' under the Guidelines, namely:
  - (a) incurred within the project period (ie from 23 July 2018 (date of execution of Grant Agreement) and 30 June 2021\*); and
  - (b) a direct cost of the project.
3. The patient related expenditure as part of the trial protocol directly supports the achievement of the planned outcomes for the project.

*\*Note that this project has requested a 12 month extension due to delays incurred at all trial sites due to COVID19 restrictions.*

Stroke Foundation awarded the grant, following independent expert peer review, to the PESTO project team in the belief that inclusion of international trial sites was consistent with the grant guidelines.

Stroke Foundation is of the view that the PESTO study design meets the 'Return to life, return to work' Clinical Research Grants criteria, which specified preference for international collaboration, and that the research is Australian-led and a significant part of the research must be carried out in Australia.

If you require any further information, please do not hesitate to contact me at [research@strokefoundation.org.au](mailto:research@strokefoundation.org.au) or 03 9670 1000.

S 22

**Chief Executive Officer**  
Stroke Foundation

**Archived:** Friday, 13 March 2026 12:30:46 AM

**From:** S 22

**Mail received time:** Tue, 21 Jul 2020 16:06:02

**Sent:** Tue, 21 Jul 2020 06:05:26

**To:** [Accelerated Research Program](#)

**Subject:** RE: MRFF Teleconference - National Stroke Foundation [DLM=For-Official-Use-Only]

**Importance:** Normal

**Sensitivity:** None

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Thanks S 22, appreciate it.

S 22

National Manager, Public Affairs & Advocacy

**Stroke Foundation**

Level 7, 461 Bourke St, Melbourne VIC3000

D S 22

StrokeLine: 1800 STROKE (1800 787 653)

S 22 [@strokefoundation.org.au](mailto:@strokefoundation.org.au)

**Email Confidentiality Statement**

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**From:** Accelerated Research Program

**Sent:** Tuesday, 21 July 2020 4:04 PM

**To:** S 22

**Cc:** Accelerated Research Program

**Subject:** RE: MRFF Teleconference - National Stroke Foundation [DLM=For-Official-Use-Only]

Good Afternoon S 22

Thank you for your email with the update on the current limitations in the recruitment of trial participants.

Please continue to keep us informed of the progress of the trial and any further changes which may occur as a result of the COVID-19 impacts.

Also, moving forward, I am your contact person in AusIndustry should you have any queries regarding the grant.

Kind Regards

S 22

S 22

National Outreach & External Grants Administration  
Victorian State Office

**AusIndustry – Support for Business**

**Phone:** +S 22

**Email:** S 22 [@industry.gov.au](mailto:@industry.gov.au)

**Internet:** [www.business.gov.au](http://www.business.gov.au)



**Business**

business.gov.au  
13 28 46  
Delivered by AusIndustry

lsb240

*The department acknowledges the traditional owners of the country throughout Australia and their continuing connection to land, sea and community. We pay our respect to them and their cultures and to the elders past and present.*

\qcFor Official Use Only

**From:** S 22 [mailto:[@strokefoundation.org.au](mailto:@strokefoundation.org.au)]  
**Sent:** Tuesday, 21 July 2020 2:19 PM  
**To:** S 22 [mailto:[@health.gov.au](mailto:@health.gov.au)]; S 22 [mailto:[@health.gov.au](mailto:@health.gov.au)]; S 22 [mailto:[@health.gov.au](mailto:@health.gov.au)]; S 22 [mailto:[@health.gov.au](mailto:@health.gov.au)]; S 22 [mailto:[@health.gov.au](mailto:@health.gov.au)]; Accelerated Research Program <[arp@industry.gov.au](mailto:arp@industry.gov.au)>  
**Cc:** S 22 [mailto:[@industry.gov.au](mailto:@industry.gov.au)]  
**Subject:** RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

Afternoon all,

I am writing to provide an update on the Perispinal Etanercept to improve Stroke Outcomes (PESTO) trial.

Trial recruitment has been placed on hold. Recruitment was placed on hold in response to the tightening of restrictions in response to COVID-19 by the Victorian Government.

While it cannot recruit, the PESTO team is continuing to work to ensure site approvals are established to proceed with recruitment safely and to avoid rescheduling appointments with participants.

Hopefully, the situation will improve soon and I will be able to provide a more positive update.

If I can provide additional details please let me know.

Stay well and safe!

S 22

\ntblS 22

\ntblNational Manager, Public Affairs & Advocacy

\ntbl\itap3Stroke Foundation

\ntbl\itap5Level 7, 461 Bourke St\ntbl\itap5,\ntbl\itap5Melbourne\ntbl\itap5\ntbl\itap5VIC\ntbl\itap5\ntbl\itap53000  
\ntbl\itap5D 03 9918 \ntbl\itap5 \ntbl\itap5T 03 9670 \ntbl\itap5 \ntbl\itap5Media 0408 000 \ntbl\itap5 S 22  
7278 > 1000 > 409 > [849](#)

\ntbl\itap3StrokeLine: 1800 STROKE (1800 787 653)

\intb1 **Please note:** Stroke Foundation stands firm in our mission to prevent stroke, save lives and enhance recovery. Essential services like StrokeLine, website and online communities continue. Operations from Stroke Foundations offices where possible have been suspended for the wellbeing of our team and the community we serve. We are working virtually, ensuring we are there when and where the stroke community needs us most. I remain available so do not hesitate to reach out by phone or email.



\intb1

\intb1The Stroke Foundation acknowledges the ancestors and traditional custodians of the land on which our offices stand and pay respect to Elders past, present and emerging.

This e-mail may contain confidential information. This message and any attachments are for the addressee only. If you have received it in error, please notify the sender. The legal effect of this e-mail is subject to its compliance with the Stroke Foundation. All e-mails sent to the Stroke Foundation may be monitored, stored and used by the company for any lawful purpose. The Stroke Foundation prohibits transmission of inappropriate material to its e-mail addresses. Any personal comments contained within this message are those of the sender not of the Stroke Foundation. The Stroke Foundation provides no assurance that this e-mail or any attachments are free of software viruses or that the opening or execution of the attachment will not cause harm to the computer systems of the Recipient and accepts no liability whatsoever for any damage of whatsoever nature, caused by such a virus.

**Archived:** Wednesday, 18 March 2026 3:59:53 PM

**From:** S 22

**Mail received time:** Wed, 9 Jun 2021 11:52:20

**Sent:** Wed, 9 Jun 2021 01:51:45

**To:** [Accelerated Research Program](#)

**Cc:** S 22

**Subject:** Approved - RE: EPCD000019 National Stroke Progress Report Assessment [SEC=OFFICIAL:Sensitive]

**Importance:** Normal

**Sensitivity:** None

All

The progress report submitted by the National Stroke Foundation for the Australian Living Guidelines for Stroke Management and Return to Life, Return to Work Stroke Recovery for young survivors project and related payment of S 47G is approved. Please advise the Grantee and organise for payment to progress.

Thanks

S 22

S 22

Director

Health and Medical Research Office | Health Economics & Research Division | Department of Health

p: S 22

S 22 )

\sb240GPO Box 9848, Canberra ACT 2601

Sirius Building | S 22

\sb240

**From:** Accelerated Research Program

**Sent:** Tuesday, 8 June 2021 2:31 PM

**To:** S 22

**Cc:** S 22 ; Accelerated Research Program

**Subject:** EPCD000019 National Stroke Progress Report Assessment [SEC=OFFICIAL:Sensitive]

Dear S 22 and team,

Please find attached the progress report assessment for National Stroke Foundation EPCD000019. S 47G

The following documents have been attached –

- BGH Progress Report Assessment

- BGH Portal progress report

- Additional information requested by BGH

- Other documents lodged by the Grantee

- Executed Grant Agreement

- Executed Agreement of Variation

Please advise of your approval of this progress report and payment or if you require any other further information.

Thanks

S 22

\qcOFFICIAL: Sensitive

\qcOFFICIAL: Sensitive

\f0

\f0"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."



Australian Government  
Department of Health

Medical Research  
Future Fund



## Medical Research Future Fund Progress and Final Report Checklist

Grant ID	EPCD000019
Institution/Organisation	National Stroke Foundation
Grant Title	S 22 2. "Return to life, return to work" stroke recovery for young survivors
Month and Year	December 2021
ANZCTR Trial ID	(where relevant)
Total Value of Grant	\$2,500,000
Value of Payments to date	\$2,500,000
Next Payment Due Date	N/A

In alignment with the reporting requirements for MRFF grants, I can confirm that the following information has been supplied by the grantee and is being forwarded to the Department of Health to inform its review of grant progress and/or completion:

<b>Adequate responses to all compulsory questions and tables</b> <i>There should be no placeholder text or single-line responses.</i>	<input checked="" type="checkbox"/>
<b>Information on variation(s), where applicable</b> <i>Where grants have or have requested variations, these have been correctly reported.</i>	<input checked="" type="checkbox"/>
<b>Information on progress against Measures of Success</b> <i>This is applicable for grants funded from November 2020 onwards, where the grant guidelines specified submission of a Measures of Success statement with applications.</i>	<input type="checkbox"/>
<b>Agreed evidence to demonstrate successful completion of the project</b> <i>This is relevant for final reports only.</i>	<input type="checkbox"/>
<b>Copies of any published reports and promotional material</b> <i>This is relevant for final reports only.</i>	<input type="checkbox"/>

Any additional relevant information

Acting officer at BGH	S 22		04/ 02/22
Reviewing officer at BGH	S 22		09/ 02 /22

## Schedule 2 Reporting requirements

### Appendix 1

Medical Research Future Fund: “Return to life, return to work”. A targeted clinical research investment in stroke recovery for young survivors.

#### Progress report requirements

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Commonwealth reserves the right to amend or adjust the requirements.

You must submit your report via the business.gov.au [portal](#) when it is complete.

#### Project Information

Grant ID: EPCD000019

Institution/Organisation: National Stroke Foundation

Grant Title: Emerging Priorities and Consumer Driven Research Initiative (July 2018)

Month and Year: January 2022 (Reporting period 01/01/2021 – 31/12/2021)

Australia New Zealand Clinical Trials Registry Trial ID (where relevant):

Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976

Early vocational intervention for people after stroke: A randomised pilot trial: ACTRN12619001164189

#### Project Progress

1. Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement or (if applicable) previous progress report, and any additional approved milestones.

The Comments field should summarise progress at the end of the reporting period towards completion of the agreed research activities relevant to each milestone/objective, and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/ Anticipated End Date	Current % Complete	Comments
1. Project start date	30/07/2018	30/07/2018	100%	
2. Call for research applications concludes	31/12/2018	30/11/2018	100%	
3. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	28/06/2019	100%	PESTO - ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration-22/09/2020. S 22

Milestone/Objective	Agreed End Date	Actual/ Anticipated End Date	Current % Complete	Comments
4. Training of staff at trial sites concludes	31/12/2019	27/10/2020	100%	PESTO - Austin Health- 27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) - 17/12/2020 & 14&18-01/2021. Alfred Health 09/04/2021.  S 22
5. Publication of study protocol and statistical analysis plan	30/04/2022	PESTO - 31/12/2022 S 22	70%	PESTO – Study protocol (21/01/2022), submission for publication planned for May 2022. Statistical analysis plan to be finalised in September 2022.  S 22
6. Patient recruitment concludes	30/04/2022	PESTO – 15/09/2022 S 22	50%	PESTO – Recruitment planned to end by mid-September 2022 for 'Last patient, last visit' by November 2022. Current recruitment = 61 randomised participants/160 targeted.  S 22
7. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	70%	Data Safety and Monitoring Committee established and performing for both trials. Data safety and monitoring extends until project completion.

Milestone/Objective	Agreed End Date	Actual/ Anticipated End Date	Current % Complete	Comments
8. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2022	31/12/2022	40%	As per trial project plans. Trials aim to maximise recruitment opportunity in 2022 within existing budget and project timeline. Publication of findings expected through 2023.  PESTO - Time between 'Last patient, last visit' (October and 31 December 2022) permits site closure, statistical analysis, top line results reported and submitted for conference presentation.
9. Project end date	31/12/2022	31/12/2022	40%	

2. Describe progress towards completion of any additional research activities undertaken during the reporting period that are not captured in the table above.

PESTO - To boost recruitment, in November 2021, Australian Stroke Clinical Registry (AuSCR) mailed out 483 letters to eligible registrants for the PESTO study. 20 responses were received out of the 480 letters sent. On 18 January 2022 AuSCR sent out 420 2<sup>nd</sup> attempt letters to eligible registrants. This has resulted in another 4 patients being randomised as trial participants. AuSCR are also working in parallel to determine if they can find alternative ways to identify patients with moderate to severe disability for eligible registrants pre-2014. Training of staff at the Alfred trial site occurred on 9<sup>th</sup> April 2021.

3. Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during the reporting period.

PESTO – Focus continues on recruitment. With COVID-19 restrictions easing in Australia, many interstate patients have been re-contacted to book/rebook their dosing visits.

Additional recruitment efforts have been made through established networks, including:

- Working with Australian Stroke Clinical Registry (AuSCR) who have reached out to eligible registrants.
- Stroke Foundation and the Australian Stroke Coalition support for promotion of the trial to community members, through EnableMe newsletters, website posts, social media, and circulation among clinical networks to increase clinician referrals to the trial.

The New Zealand PESTO site ran a second Facebook advertisement campaign, based on initial success through this channel in reaching eligible patients, however the second campaign did not yield results in recruiting new patients. This may have been due to travel restrictions, limited population of eligible participants within reasonable traveling distance and vaccine requirements interfering with timing of injection (co-injection of etanercept with COVID-19 vaccination may interfere with COVID-19 vaccination efficacy).

The PESTO steering committee is considering a Facebook advertising campaign in Victoria and reallocation of project budget to boost recruitment. Additionally, the steering committee is considering relaxing inclusion criteria to allow patients with less severe disability to participate in the trial and older participants to the trial.

S 22

S 22

4. Complete the following table for all variation requests approved, submitted (pending approval) or in draft (pending submission) for this grant to date.

Description of Variation	Current Status (Approved/Submitted/In Draft)
Project Duration Variation to extend to 31 December 2022	Approved

5. Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay.

PESTO - Recruitment has increased and with recruitment extension to December 2022, the recruitment target remains the goal. The Austin site is recruiting on average 2 patients per week. With COVID-19 restrictions lifted, the Austin site has re-engaged contact with interstate participants and booking in patients. Additionally, the AuSCR mailout has increased interest. Other sites remain slower with recruitment, with New Zealand having difficulty recruiting because of COVID-19 restrictions in the North Island. Currently 38 percent of recruitment is complete with 61/160 patients randomised and interest in the trial has increased with numerous requests for participation. The target recruitment rate is 3 patients per week to permit 'last patient, last visit' on 15<sup>th</sup> September 2022.

S 22

6. Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes.

You should include information about your proposed approach and any key enablers or barriers to implementation.

PESTO - Since the last progress report, awareness of the study and its potential outcomes has been increased by presentation of abstracts at the Stroke Society of Australasia and the World Stroke Conference. A Facebook campaign was run in New Zealand. Stroke Foundation has communicated via social media channels and EnableMe to the target audience. The AuSCR registry has performed two mailouts to potential trial participants reaching 483 patients. The research team will further publish the study protocol in an international journal. As the trial results are still pending, implementation of this unproven therapy is not yet required.

S 22

S 22

S 22

7. Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.

**Question 7 applies to grants where the funded organisation is responsible for supporting research projects led by other organisations.**

Partner Organisation	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided	Start Date of Project	% Project Complete
Not applicable						

## Project Expenditure

8. Provide details of all expenditure incurred during the reporting period.

Expenditure should be divided into the same categories as the budget in your grant agreement. The table should indicate budgeted and actual expenditure for the current reporting period. The Comments field should justify any differences between the budgeted and actual expenditure.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or contact us if you have any questions about expenditure.

S 47G

9. Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, explain why.

S 47G

The “Return to life, return to work” research teams have successfully reallocated the project budget to meet the revised delivery timeframes and trial objectives.

Please refer Attachment 4: Project Expenditure Table submitted with Progress Report 3 (January 2021).

10. Provide details of the estimated expenditure for the next reporting period.

Expenditure Item	Budget (AUD)
Other eligible expenditure	\$ 47G

11. Provide details of any partner contributions received during the reporting period.

The Comments field should indicate whether each contribution has been made as expected. If not, describe the impact of any delays or changes on the delivery of the Research Activity.

Name of Partner	Type of Contribution	Value of Contribution	Comments
Not applicable			

## Project Evaluation

The [MRFF Monitoring, Evaluation and Learning Strategy](#) was published in November 2020.

**Question 12 must be completed if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. N/A**

12. Complete the following table for each outcome or result against which your contribution to the Measures of Success for the MRFF is being evaluated, as specified in the Measures of Success statement provided with your application.

For each Measure of Success, the table should:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

You may list several outcomes/results against a single Measure of Success.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress

13. Provide a statement on the most important finding or outcome from your research during the reporting period, including any new or unexpected findings or outcomes.

Noting that your response may be used in public communications about the MRFF, please indicate whether any of the information you provide is commercial in confidence.

PESTO - The trial results are yet unknown and no new unexpected findings or outcomes were observed. Recruitment through the Australian Stroke Clinical Registry has however led to local

trial awareness and interest and provides an important avenue for future trial recruitment for stroke clinical trials.

S 22

14. Describe any enablers or barriers to the translation or implementation of your research that could be used to inform future MRFF funding opportunities.

PESTO - The biggest barrier to project completion has been the impact of COVID-19.

For future opportunities, realistic timelines for clinical trials would be welcomed. Additionally, support for travel costs, advertising on social media and permission to expend funds overseas would increase future recruitment rates and speed up trial completion.

S 22

## Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.

you are aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

# Application EPCD000019

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## Report Summary

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**Report**

Adhoc report

**Report Type**

Ad hoc

**Due Date**

31/01/2022 12:00:00 AM

**Status**

Submitted

**Submitted Date**

31/01/2022 1:52:44 PM

**Submitted By**

S 22

## Bank account details

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### Bank account questions

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Have your bank account details changed since your last payment or since you last provided them?

If yes, we will provide you with a form to complete your new bank account details.

If you are not due any further payments, select not applicable.

No

## Attachments

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### Agreed evidence

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## Completed Progress Report

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Please attach your completed Progress Report using the template provided by the Business Grants Hub.

**Completed Progress Report**

Please attach your completed Progress Report using the template provided by the Business Grants Hub.

2021 MRFF EPCD000019 Progress Report\_Guidelines 2022-01 SUBMISSION.pdf

2021 MRFF EPCD000019 Progress Report\_RTLRTW Research 2022-01 SUBMISSION.pdf

## Additional documents

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**Additional supporting information**

If you need to provide additional documents such as copies of published reports etc related to the project, you should attach them here.

Att 1 Stroke Living Guidelines evaluation (June 2021).pdf

Att 2 Consumer engagement in Stroke Living Guidelines (June 2021).pdf

Att 3 RTW Knowledge and Dissemination Plan (January 2020).pdf

Att 4 Project Expenditure Table submitted with Progress Report 3 (January 2021).pdf

## Declaration

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## Report Declaration

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I am authorised by the grantee to submit this report and certify that:

- the information in this report is accurate, complete and not misleading and that I understand the giving of false or misleading information is a serious offence under the *Criminal Code Act 1995*(Cth)
- the activities undertaken and the expenditure incurred is in accordance with the grant agreement
- I am aware of the grantee's obligations under their grant agreement
- I am aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

**By checking this box I agree to all of the above declarations and confirm all of the above statements to be true**

Yes



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Department of Health and Aged Care

Medical Research  
Future Fund



## Progress Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through progress reports. For varying your grant and grant agreement please refer to the [MRFF Grant Variation Policy](#).

Please ensure that you are using the latest version of the Progress Report template. You must submit your report on the business.gov.au [portal](#). You can enter the required information in stages and submit when it is complete.

### Project Information

Grant ID	EPCD000019
Grant Opportunity Name	Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation)
Administering Organisation	National Stroke Foundation
Chief Investigator A / Project Lead	S 22 (National Stroke Foundation) S 22 (Return to life PESTO) S 22 (Return to work)
Grant Title	Emerging Priorities and Consumer Driven Research Initiative (July 2018)
Grant Agreement Start and End Dates	23/07/2018 – 30/06/2024
Research Activity Start and End Dates	30/07/2018 – 31/12/2023
Australia New Zealand Clinical Trials Registry Trial ID (where relevant)	'Return to life' - Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976  S 22
Reporting Period	From 01/01/2022 – 31/12/2022
If the Commonwealth Commercialisation Clauses apply to this project, have there been any changes to the Commercialisation Plan?	No
Do you plan to execute any new agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	No

### Project Progress

1. Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement.

The comments field should clearly summarise progress at the end of this reporting period towards completion of the agreed research activities relevant to each milestone/objective and provide a justification for any changes or delays to milestones/objectives.



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#### **A. Return to life PESTO**

Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
1. Project start date	30/07/2018	30/07/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
3. Successful applicant engaged	31/03/2019	18/03/2019	100%



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Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
<b>Comments:</b> Following competitive grant application and independent review process administered by Stroke Foundation.			
4. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	28/06/2019	100%
<b>Comments:</b> PESTO - ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration 22/09/2020.			
5. Training of staff at trial sites concludes	31/12/2019	27/10/2020	100%
<b>Comments:</b> PESTO - Austin Health - 27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) - 17/12/2020 & 14&18-01/2021. Alfred Health 09/04/2021.			
6. Approved international trial sites on boarded	31/12/2020	17/12/2020	100%
<b>Comments:</b> As per previous correspondence dated 12/05/2021.			
7. Patient recruitment strategy and contingency plans - ongoing until project end	31/12/2021	31/12/2021; 31/12/2022	100%
<b>Comments:</b> On top of recruitment strategies (close collaboration with Stroke Foundation's EnableMe platform, word of mouth via recruited patients), the team have slightly amended entry criteria into the trial permitting a larger pool of patients to participate in the trial. In addition, the team have pre-screened a list of 495 potential candidates for the trial from one of the participating sites and are planning to contact 60 patients for interest. Additionally, two new mailouts with the revised criteria will be sent through the Australian Stroke Clinical Registry. It is anticipated that these strategies will permit complete recruitment by end of 2023.			
8. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%
<b>Comments:</b> First Data Safety Monitoring Board (DSMB) meeting was held: advise to continue trial as planned.			
9. Study protocol review by Steering and Ethics Committees – as required	31/12/2022	31/12/2022	100%
<b>Comments:</b> A second amendment was approved by the lead HREC and adopted by recruiting sites.			
10. Publication of study protocol and statistical analysis plan	30/06/2023	30/06/2023	70%
<b>Comments:</b> Draft of protocol written and will be circulated now that that final protocol amendments have been approved by steering committee and HRECs. Slightly delayed publication upon advice of the trial statistician. Statistical analysis plan will be written during period February and June 2023. On hold until approval by HREC upon advice of the trial statistician.			
11. Patient recruitment concludes	31/12/2023	31/12/2023	60%
<b>Comments:</b> The project has currently enrolled 97/160 patients (60% complete from 38% at end of 2021). Additional patients have been screened and are planned in coming weeks/months. For additional planned recruitment strategies see comments under Milestone 7.			
12. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2023	31/12/2023	0%
<b>Comments:</b> Not applicable			
13. Project end date	31/12/2023	31/12/2023	0%
<b>Comments:</b> Not applicable			

S 22



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S 22

2. Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)

S 22

2. Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)

**A. Return to life PESTO**

As captured in the table above.



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2. Describe the status of the project and progress towards completion of any additional research activities undertaken during this reporting period that are not captured in the table above. (min 200, max 300 words)

S 22

3. Complete the following table for all variation requests under the MRFF Grant Variation Policy approved, submitted (pending approval) or in draft (pending submission) for this grant to date.

Type of Variation	Description of Variation	Current Status
Defer an in-progress grant	Variation due to 'external delays in the provision of research data or outcomes critical to progression of the grant'. Activity Completion varied to 31 December 2022; Agreement End Date varied to 30 June 2023. Executed 7 June 2021.	Approved
Defer an in-progress grant	Variation due to 'external delays in the provision of research data or outcomes critical to progression of the grant'. Activity Completion varied to 31 December 2023; Agreement End Date varied to 30 June 2024. Executed 28 October 2022.	Approved

4. Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)

S 22

4. Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)

#### **A. Return to life PESTO**

The biggest risk to the PESTO project is the slower than anticipated recruitment over the duration of the project. The project has currently enrolled 97/160 trial participants (60% recruitment rate).

S 47G



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Department of Health and Aged Care

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To closely monitor recruitment rates and develop strategies to support recruitment, the project team have monthly meetings with Stroke Foundation and regular meetings with the PESTO steering committee.

The project team has hired additional staff to help with responding to queries from interested patients, ensuring close follow up and facilitation of recruitment of interested candidates.

4. Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during this reporting period. Please attach an updated risk management plan if the risk to your project is high. (min 200, max 300 words)

S 22

5. Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)

S 22

5. Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)

#### **A. Return to life PESTO**

As reported on 29/07/2022, progress towards completion of the trial has been delayed due to the impact of COVID-19. During 2022, an updated project plan was implemented, and an extension to 31/12/2023 was granted. The team anticipate that its recruitment strategies and current resourcing will achieve trial completion in December 2023.

5. Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay. (min 200, max 300 words)

S 22



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**Department of Health and Aged Care**

Medical Research  
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6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

You should include information about any key enablers or barriers to implementation you have faced and your proposed approach to translation.

S 22

6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

S 47G

6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes. (min 200, max 300 words)*

S 22



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S 22

7. Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.

This question applies only to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
N/A						

## Project Expenditure

8. Provide details of all expenditure incurred using MRFF funding during this reporting period and the estimated expenditure for the next reporting period.

Expenditure should be divided into the same categories as the budget in your grant agreement.

The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), to date for the budget item (D) and estimated for next period (E).

The comments field (F) should justify any differences between the budgeted and actual expenditure for the current reporting period, including any details of anticipated expenditure or any downstream effects of these differences.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact [mrff@industry.gov.au](mailto:mrff@industry.gov.au).

S 47G



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Department of Health and Aged Care

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Future Fund



9. Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)

The funds have been expended according to the grant opportunity guidelines. This has been ratified by Stroke Foundation and the administering institutions of each project activity.

10. Provide details of any partner contributions received during this reporting period and indicate whether each contribution has been made as expected. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.

If a contribution has not been made as expected, describe the impact of any delays or changes to the delivery of the Research Activity. If the project does not have partners that committed to make cash or in-kind contributions, select N/A in the table below.

Name of Partner	Type of Contribution	Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
	N/A			

## Project Evaluation

11. Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the [MRFF Monitoring, Evaluation and Learning Strategy \(November 2020\)](#) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were required to be submitted with the application, select N/A in the first row of the table below.

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.)
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

Add rows as necessary.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress
N/A			
Select			

12. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)



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Note that your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

S 22

12. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)

**A. Return to life PESTO**

The PESTO team prefer that, pending the outcome of the trial, no official communication is publicised.

12. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences the most important finding(s) or outcome(s) from your research, if any, during this reporting period, and why they are important. (min 200, max 300 words)

S 22

## Attachments

Attach any agreed evidence required above (e.g. updated risk management plan).

Nil.

## Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

7 November 2019

S 22

National Manager Clinical Services  
Stroke Foundation  
Level 14, 477 Pitt Street  
Sydney NSW 2000

S 22

Dear Mr S

**NHMRC CEO approval of the amended recommendations in the *Clinical guidelines for stroke management*.**

I am pleased to inform you that Professor Anne Kelso AO, the Chief Executive Officer of the National Health and Medical Research Council (NHMRC), approved the minor amendments to the *Clinical guidelines for stroke management 2017* (the guidelines) on 7 November 2019. Professor Kelso made this decision on the advice of NHMRC Council under section 14A of the *National Health and Medical Research Council Act 1992*.

The approved amendments relate to thrombolysis, acute antiplatelet therapy and patent foramen ovale closure and are the draft recommendations submitted by the Stroke Foundation to NHMRC on 10 September 2019.

As required by legislation, NHMRC will publish a notice on the NHMRC website advising of the amendments to the guidelines. The amendments are required to be acknowledged in the NHMRC approval text. Please contact S 22 regarding the revised approval text on 03 8866 0404 or via email at [clinicalguidelines@nhmrc.gov.au](mailto:clinicalguidelines@nhmrc.gov.au).

Regards,

S 22

Director, Clinical Practice Guidelines



Monday 18 March 2019

## Return to Life, Return to Work research grants announced

Australia's working age stroke survivors are set to benefit from research into innovative recovery and rehabilitation clinical interventions.

Stroke Foundation today announced the recipients of the \$1 million 'Return to life, return to work' clinical research grants for 2019.

Funded by the Federal Government through the Medical Research Future Fund, the research package includes Australia's first multicentred clinical trial of Perispinal Etanercept in chronic stroke.

Stroke Foundation Research Advisory Committee Chair Professor Amanda Thrift said the grants were an investment into the future of Australia's younger stroke survivors.

"Around 142,500 Australian stroke survivors are of working age. International evidence shows incidence of stroke among young people is increasing, so we must do more to ensure tailored services and supports are available," Professor Thrift said.

"Stroke strikes the brain and can leave a lasting impact on independence, family life, finances and careers – particularly for those in their 20s to 50s.

"While advancements in acute stroke treatment mean more Australians are surviving than ever before, recovery can be a long and challenging journey physically, cognitively and mentally.

"This funding package has the potential to provide break-through treatments to those suffering from the impact of stroke allowing them to optimise their recovery and return to the things in life which fulfil them most," she said.

Grant recipients:

- › Professor Vincent Thijs, Florey Institute of Neuroscience and Mental Health

### **Perispinal Etanercept to improve Stroke Outcomes (PESTO)**

Seeks to determine if Perispinal Etanercept improves quality of life in working age patients who have a history of stroke and moderate to severe disability. It will also investigate if repeated treatments lead to improved quality of life compared to one treatment.

- › Associate Professor Natasha Lannin, School of Allied Health, Latrobe University, Alfred Health

### **Does an embedded vocational rehabilitation intervention improve employment outcomes above and beyond standard stroke rehabilitation?**

The grant will fund a pilot project to test the feasibility and potential benefit of building on current clinical rehabilitation by adding an embedded 12 week targeted vocational rehabilitation.

**Media Contact:** Peta James ph. 0408 000 409 e: [media@strokefoundation.org.au](mailto:media@strokefoundation.org.au)







**Austin Hospital**

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Telephone 03 9496 5000  
Facsimile 03 9458 4779  
www.austin.org.au

**AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE**  
**ETHICAL APPROVAL**

Professor Vincent Thijs  
Austin Health

05 September 2019

Dear Prof Thijs,

**HREC Reference Number:** HREC/54900/Austin-2019

**Austin Health SITE REFERENCE Number:** DT 19/54900

**Project Title:** A Prospective multicentre, phase 2b randomised controlled double-blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment

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I am pleased to advise that the above project has **received ethical approval** from the Austin Health Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007, updated 2018). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007, updated 2018), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

**HREC Approval Date:** 5/09/2019

**Ethical approval for this project applies at the following sites:**

Site
Austin Health
Alfred Health

**Approved Documents:**

The following documents have been reviewed and approved:

Document	Version	Date
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HREA (HREC54900/Austin-2019-184067(v2))		13/08/2019
VSM	3	12/08/2019
Protocol	1	19/07/2019
Etanaercept Product Information		01/04/2019
PESTO CRF	1	13/08/2019
Master PICF	1	13/08/2019
Master Person Responsible ICF	1	13/08/2019
Advertising	1	28/05/2019

### Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site-specific assessment application.

### Conditions of Ethics Approval:

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
  - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products November 2016*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters, which may affect the conduct of the project.
- **If your project involves radiation:**
  - **It is your responsibility to ensure the research is added to the site Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check your Medical Physicist Report). The site RGO must be notified when the research has been added to the licence.**
  - **You are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice**



**'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005) (ARPANSA Code).**

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

**Lisa Pedro Manager, Ethics and Research Governance**

Office for Research, Austin Health

Level 8 HSB.

E-mail: [ethics@austin.org.au](mailto:ethics@austin.org.au)

Web: <http://www.austin.org.au/researchethics>



*Insert Header with institution's name or institution's letterhead*

## Participant Information Sheet/Consent Form

**Interventional Study - Adult providing own consent**

*[Insert site name]*

<b>Title</b>	A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.
<b>Short Title</b>	Perispinal Etanercept to improve STroke Outcomes (PESTO)
<b>Protocol Number</b>	<i>Version 1 dated 19 July 2019</i>
<b>Project Sponsor</b>	<i>Florey Institute of Neuroscience and Mental Health</i>
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Professor Vincent Thijs / <i>Principal Investigator</i>
<b>Location</b>	<i>[Location]</i>

### Part 1 What does my participation involve?

#### 1 Introduction

You are invited to take part in this research project. This is because you have had a stroke within the last 5 years and have ongoing disability and impairments. The research project is testing a new treatment for stroke called Etanercept.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

#### 2 What is the purpose of this research?

Master Participant Information Sheet/Consent Form 13 August 2019

*[Site Name]* Site Master Participant Information Sheet/Consent Form *[Date]*

Local governance version *[Date]* (Site PI use only)

Stroke survivors often have lifelong, disabling effects as a result of their stroke which impact daily life. Because current treatment options for post-stroke impairments are limited, stroke survivors sometimes try out therapies that may not be scientifically proven.

The use of Etanercept injected at the base of the neck, is one treatment that has received a lot of attention in the media as it has been linked with improvement of stroke symptoms. It is unclear whether these improvements are due to the drug or other factors, as many of the effects have been seen in small observational case studies.

Etanercept is approved in Australia to treat joint conditions (such as rheumatoid arthritis) or skin conditions (such as psoriasis). However, it is not approved to treat stroke. Therefore, it is an experimental treatment for stroke. This means that it must be tested to see if it is an effective treatment for stroke.

This trial is aiming to properly test to see whether this medication is an effective treatment.

This research has been initiated by, Professor Vincent Thijs, and the project is being coordinated by the Florey Institute of Neuroscience and Mental Health, in Melbourne. This research has been funded by a grant from the Stroke Foundation.

### **3 What does participation in this research involve?**

If you are eligible, you will be invited to participate and if you agree, you will be asked to sign a consent form. This will happen before any study related assessments take place.

You will be participating in what is called a randomised controlled study. When we do not know which treatment is best for treating a condition, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are similar, each participant is put into a group by chance (random).

You will be randomly assigned to receive an injection of Etanercept or an injection of a placebo at two timepoints in the study.

A placebo is a substance that looks like the real thing but is not and does not have any active ingredients.

The study will be double-blinded. This means that neither you nor your study doctor will know which treatment you are receiving. However, your study doctor can find out which treatment you are receiving if necessary, for safety reasons.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

Participation in this study will involve 4 visits to the hospital/clinic over a period of approximately 2.5 months outlined below.

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#### **4 What do I have to do?**

Participation in any research project is voluntary. If you decide to take part, you will be asked to keep your study appointments and complete all study assessments. If you cannot attend an appointment, please tell the study staff as soon as possible. They will then set a new appointment. Tell the study staff about any unusual symptoms you may have immediately. Do not wait until your next scheduled visit. Also tell them about any changes in medications, doctor or nurse appointments, or any hospital admissions that you may have had.

You will be able to continue taking your regular medications for the duration of this study and can continue with any other routine treatments for your stroke.

We ask that you do not participate in any other clinical trial for the duration of this trial. This is because results can be mixed up if there is more than one treatment being tested at any one time.

#### **5 Other relevant information about the research project**

Approximately 168 participants will be involved in this study. This study is being conducted in hospitals in Australia and the UK.

#### **6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with this hospital.

#### **7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include ongoing physiotherapy, occupational therapy, speech therapy, psychological support, orthoses, spasticity management and pain control. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

#### **8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research. Even if there is no direct benefit to you, others may benefit from what is learned in this study.

#### **9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

### **Blood sample collection**

Insertion of a needle for blood collection may cause slight pain or bruising at the site. In rare cases the injection site could become infected. For some participants, there is a rare risk of fainting due to having the blood sample taken.

### **Study treatment**

This is an injection of a small volume of liquid (1mL) under the surface of the skin at the base of the neck. Bruising or pain at the injection site is possible. There is a rare chance of infection at the injection site. After the injection you might feel a bit uncomfortable when the bed is tilted with your head down.

### **Reported side effects of Etanercept**

Many of the reported side effects have occurred in patients receiving other medicines at the same time which affect immunity, or in patients with other diseases that could make them more likely to catch infections.

- Infections that have been reported with the use of Etanercept include sepsis (blood infection) upper respiratory infections. (greater than 10%)
- Allergic reactions including itching, bruising, redness, bleeding, swelling, pain, hardness or a rash around the injection site may occur in about 10% of patients.
- In rare cases tuberculosis has been reported (less than 1%). Some of these infections have caused death. During the trial participants will be monitored for signs and symptoms of infection. Participants will be closely monitored medically treated for any signs of infection that might appear and the study drug will be stopped.
- Blood abnormalities including low red or white blood cells are uncommon (less than 1%): If participants develop persistent fever, sore throat, bruising, bleeding, paleness, they should seek immediate medical advice.
- There is an increased risk of infection and death in patients with alcoholic hepatitis, and development of bowel problems in patients with juvenile idiopathic arthritis. However, these patients will not be eligible to participate.
- Non-melanoma skin cancers have been reported (less than 1%) in patients receiving etanercept.
- Malignant melanoma, lymphoma and leukemia have also been reported (less than 0.1%) in patients receiving etanercept.

### **Pregnancy and contraception:**

The effects of Etanercept on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and childbearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of 3 months after completion of the research project. You should discuss methods of effective contraception with your study doctor.

*For female participants:* If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

*For male participants:* You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

## **10 What will happen to my test samples?**

You are required to have a blood test to make sure that you don't have tuberculosis (lung infection) or hepatitis (liver inflammation) which would make you ineligible to receive Etanercept. The Samples will be tested in the hospital pathology department and results will be made available to the researchers.

The proposed blood tests include a screening test for Hepatitis. This is because the study doctors need to know if you have a history of hepatitis as Etanercept had been known to reactivate Hepatitis B and worsen Hepatitis C. You will receive information and counselling before the test. If a test shows you have Hepatitis, you will have follow-up counselling and medical advice. If your test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agree to have this testing.

## **11 What if new information arises during this research project?**

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will plan for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

## **12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, it is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain if treatments or medications need to be stopped for the time you are involved in the research project.

## **13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

## 14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as unacceptable side effects.

## 15 What happens when the research project ends?

At the end of the project a summary of the results of the project will be available through the researchers at your hospital approximately 6 months after the completion of the study. At the end of the study, the researchers will ask you if you would be happy to be contacted after the research ends.

As Etanercept is not yet an approved treatment for stroke, it will not be available to be administered for stroke immediately after the completion of this study. You should follow your routine care provided by your doctor or allied health professionals.

## Part 2 How is the research project being conducted?

### 16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. For the study, your information will be identified by a unique identification number and will be stored on a secure electronic data bank at the Florey Institute for Neuroscience and Mental Health. All information collected at the site in relation to this study will be maintained in a locked secure location for a period of 15 years after the completion of the study and will be accessible to the site researchers only. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, the Florey Institute of Neuroscience and Mental Health, the institution relevant to this Participant Information Sheet, [Name of institution], or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## 17 Complaints and compensation

If you have any complaints about the research project, you may address these with the person listed under section 20 of this form

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury, the parties involved in this research project have agreed to cover any medical costs that may be incurred.

## 18 Who is organising and funding the research?

This research project is being conducted by Professor Vincent Thijs at the Florey Institute of Neuroscience and Mental Health who has been provided funding from the Stroke Foundation to complete the project.

There is no expected financial benefit to the Florey Institute for Neuroscience and Mental Health or any of the involved researchers.

[Name of institution] will receive a payment from the Florey Institute of Neuroscience and Mental Health for undertaking this research project.

No member of the research team will receive a personal payment from your involvement in this research project (other than their ordinary wages).

## 19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

## 20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on [phone number] or any of the following people:

### Clinical contact person

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	Austin Health Human Research Ethics Committee
Telephone	03 9496 4090
Email	ethics@austin.org.au

## Consent Form - *Adult providing own consent*

**Title** A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.

**Short Title** Perispinal Etanercept to improve STroke Outcomes (PESTO)

**Protocol Number** *Version 1 dated 19 July 2019*

**Project Sponsor** *Florey Institute of Neuroscience and Mental Health*

**Coordinating Principal Investigator/** *Professor Vincent Thijs /Principal Investigator]*

**Location** *[Location where the research will be conducted]*

### **Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

### **Declaration by Participant – for participants who have read the information**

Name of Participant (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

### **Declaration - for participants unable to read the information and consent form**

Witness to the informed consent process

Name (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____	
Signature _____	Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

## Form for Withdrawal of Participation - *Adult providing own consent*

**Title** A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.

**Short Title** Perispinal Etanercept to improve STroke Outcomes (PESTO)

**Protocol Number** *Version 1 dated 19 July 2019*

**Project Sponsor** *Florey Institute of Neuroscience and Mental Health*

**Coordinating Principal Investigator/  
Principal Investigator** *Professor Vincent Thijs /**Principal Investigator***

**Location** *[Location where the research will be conducted]*

### **Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

Name of Participant (please print) _____
Signature _____ Date _____

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### **Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher <sup>†</sup> (please print) _____
Signature _____ Date _____

<sup>†</sup> A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

*Insert Header with institution's name or institution's letterhead*

## Participant Information Sheet/Consent Form – Person Responsible/Medical treatment decision maker

**Interventional Study** - *Person responsible/Medical treatment decision maker consenting on behalf of participant*

*[Insert site name]*

**Title**

A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.

**Short Title**

Perispinal Etanercept to improve STroke Outcomes (PESTO)

**Protocol Number**

*Version 1 dated 19 July 2019*

**Project Sponsor**

*Florey Institute of Neuroscience and Mental Health*

**Coordinating Principal Investigator/  
Principal Investigator**

*Professor Vincent Thijs /**Principal Investigator***

**Location**

*[Location]*

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### Part 1 What does participation involve?

#### 1 Introduction

The participant is invited to take part in this research project. This is because the participant has had a stroke within the last 5 years and has ongoing disability and impairments. The research project is testing a new treatment for stroke called Etanercept.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the participant to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the participant can take part, you might want to talk about it with a relative, friend or the participant's local doctor.

Participation in this research is voluntary. If you don't wish the participant to take part, the participant doesn't have to. They will receive the best possible care whether or not they take part.

If you decide you want the participant to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to the participant taking part in the research project
- Consent to the participant having the tests and treatments that are described
- Consent to the use of the participant's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

Master Participant Information Sheet/Consent Form 13 August 2019

*[Site Name]* Site Master Participant Information Sheet/Consent Form *[Date]*

Local governance version *[Date]* (Site PI use only)

## **2 What is the purpose of this research?**

Stroke survivors often have lifelong, disabling effects as a result of their stroke which impact daily life. Because current treatment options for post-stroke impairments are limited, stroke survivors sometimes try out therapies that may not be scientifically proven.

The use of Etanercept injected at the base of the neck, is one treatment that has received a lot of attention in the media as it has been linked with improvement of stroke symptoms. It is unclear whether these improvements are due to the drug or other factors, as many of the effects have been seen in small observational case studies.

Etanercept is approved in Australia to treat joint conditions (such as rheumatoid arthritis) or skin conditions (such as psoriasis). However, it is not approved to treat stroke. Therefore, it is an experimental treatment for stroke. This means that it must be tested to see if it is an effective treatment for stroke. This trial is aiming to properly test to see whether this medication is an effective treatment.

This research has been initiated by, Professor Vincent Thijs, and the project is being coordinated by the Florey Institute of Neuroscience and Mental Health, in Melbourne. This research has been funded by a grant from the Stroke Foundation.

## **3 What does participation in this research involve?**

If they are eligible, they will be invited to participate and if you agree, you will be asked to sign a consent form. This will happen before any study related assessments take place.

They will be participating in what is called a randomised controlled study. When we do not know which treatment is best for treating a condition, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are similar, each participant is put into a group by chance (random).

The participant will be randomly assigned to receive an injection of Etanercept or an injection of a placebo at two timepoints in the study.

A placebo is a substance that looks like the real thing but is not and does not have any active ingredients.

The study will be double-blinded. This means that neither you, the participant nor their study doctor will know which treatment they are receiving. However, the study doctor can find out which treatment they are receiving if necessary, for safety reasons.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All medication, tests and medical care required as part of the research project will be provided free of charge.

If the participant has a local doctor, we strongly recommend that you inform them of their participation in this research project.

Participation in this study will involve 4 visits to the hospital/clinic over a period of approximately 2.5 months outlined below.

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At visit 4 the participant will have a series of tests to again determine disability from the stroke.

- They will be asked to complete a short questionnaire about their quality of life (about 30 minutes)
- They will be asked to complete a questionnaire about overall health, a questionnaire about fatigue and a questionnaire about anxiety (about 40 minutes).
- They will be asked to do a test that will tell the researchers about their thinking and to indicate if they have any pain on a visual scale (about 25 minutes).

The doctor will ask about any changes to medications since the last visit and will check to see if they have any side effects from the injection. This visit will take approximately 2.5 hours.

#### **4 What does the participant have to do?**

Participation in any research project is voluntary. If you decide to take part, the participant will be asked to keep all study appointments and complete all study assessments. If they cannot attend an appointment, please tell the study staff as soon as possible. They will then set a new appointment. Tell the study staff about any unusual symptoms the participant may have immediately. Do not wait until the next scheduled visit. Also tell them about any changes in medications, doctor or nurse appointments, or any hospital admissions that the participant may have had.

The participant will be able to continue taking regular medications for the duration of this study and can continue with any other routine treatments for stroke.

We ask that the participant does not participate in any other clinical trial for the duration of this trial. This is because results can be mixed up if there is more than one treatment being tested at any one time.

#### **5 Other relevant information about the research project**

Approximately 168 participants will be involved in this study. This study is being conducted in Australia and the UK.

#### **6 Does the participant have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish the participant to take part, the participant does not have to. If you decide that the participant can take part and later change your mind, you are free to withdraw the participant from the project at any stage.

If you do decide that the participant can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the participant can take part or not take part, or take part and then be withdrawn, will not affect the participant's routine treatment, your or the participant's relationship with those treating them, or the participant's relationship with this hospital.

#### **7 What are the alternatives to participation?**

The participant does not have to take part in this research project to receive treatment at this hospital. Other options are available; these include ongoing physiotherapy, occupational therapy, speech therapy, psychological support, orthoses, spasticity management and pain control. The participant's study doctor will discuss these options with you before you decide whether or not the participant can take part in this research project. You can also discuss the options with the participant's local doctor.

#### **8 What are the possible benefits of taking part?**

We cannot guarantee or promise that the participant will receive any benefits from this research. Even if there is no direct benefit to the participant, others may benefit from what is learned in this study.

## **9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. The participant may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If the participant has any of these side effects, or you are worried about them, talk with the participant's study doctor. The participant's study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the participant's study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the participant's study doctor may need to stop the participant's treatment. The participant's study doctor will discuss the best way of managing any side effects.

### **Blood sample collection**

Insertion of a needle for blood collection may cause slight pain or bruising at the site. In rare cases the injection site could become infected. For some participants, there is a rare risk of fainting due to having the blood sample taken.

### **Study treatment**

This is an injection of a small volume of liquid (1mL) under the surface of the skin at the base of the neck. Bruising or pain at the injection site is possible. There is a rare chance of infection at the injection site. After the injection the participant might feel a bit uncomfortable when the bed is tilted with their head down.

### **Reported side effects of Etanercept**

Many of the reported side effects have occurred in patients receiving other medicines at the same time which affect immunity, or in patients with other diseases that could make them more likely to catch infections.

- Infections that have been reported with the use of Etanercept include sepsis (blood infection) upper respiratory infections. (greater than 10%)
- Allergic reactions including itching, bruising, redness, bleeding, swelling, pain, hardness or a rash around the injection site may occur in about 10% of patients.
- In rare cases tuberculosis has been reported (less than 1%). Some of these infections have caused death. During the trial participants will be monitored for signs and symptoms of infection. Participants will be closely monitored medically treated for any signs of infection that might appear and the study drug will be stopped.
- Blood abnormalities including low red or white blood cells are uncommon (less than 1%): If participants develop persistent fever, sore throat, bruising, bleeding, paleness, they should seek immediate medical advice.
- There is an increased risk of infection and death in patients with alcoholic hepatitis, and development of bowel problems in patients with juvenile idiopathic arthritis. However, these patients will not be eligible to participate.
- Non-melanoma skin cancers have been reported (less than 1%) in patients receiving etanercept.
- Malignant melanoma, lymphoma and leukemia have also been reported (less than 0.1%) in patients receiving etanercept.

**Pregnancy and contraception:**

The effects of Etanercept on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. The participant must not participate in the research if they are pregnant or trying to become pregnant, or breast-feeding. If the participant is female and child-bearing is a possibility, they will be required to undergo a pregnancy test prior to commencing the research project.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of 3 months after completion of the research project. The participant should discuss methods of effective contraception with their study doctor.

*For female participants:* If the participant does become pregnant whilst participating in the research project, you should advise the participant's study doctor immediately. The participant's study doctor will withdraw her from the research project and advise on further medical attention should this be necessary. The participant must not continue in the research if she becomes pregnant.

*For male participants:* You should advise the study doctor if the participant fathers a child while participating in the research project. The participant's study doctor will advise on medical attention for the participant's partner should this be necessary.

**10 What will happen to the participant's test samples?**

The participant is required to have a blood test to make sure that they don't have tuberculosis (lung infection) or hepatitis (liver inflammation) which would make them ineligible to receive Etanercept. The Samples will be tested in the hospital pathology department and results will be made available to the researchers.

The proposed blood tests include a screening test for Hepatitis. This is because the study doctors need to know if the participant has a history of hepatitis as Etanercept had been known to reactivate Hepatitis B and worsen Hepatitis C. The participant will receive information and counselling before the test. If a test shows they have Hepatitis, they will have follow-up counselling and medical advice. If the test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agree to this.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the participant's study doctor will tell you about it and discuss whether you want the participant to continue in the research project. If you decide to withdraw the participant, their study doctor will make arrangements for their regular health care to continue. If you decide that the participant can continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the participant's study doctor might consider it to be in the participant's best interests to be withdrawn from the research project. If this happens, the doctor will explain the reasons and arrange for the participant's regular health care to continue.

**12 Can the participant have other treatments during this research project?**

Whilst participating in this research project, it is important to tell the study doctor and the study staff about any treatments or medications the participant may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during participation in the

research project. The study doctor should also explain if treatments or medications need to be stopped for the time the participant is involved in the research project.

### **13 What if I withdraw the participant from this research project?**

If you decide to withdraw the participant from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing

If you do withdraw the participant during the research project, the study doctor and relevant study staff will not collect additional personal information from the participant, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw the participant will form part of the research project results. If you do not want them to do this, you must tell them before joining the research project.

### **14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as unacceptable side effects.

### **15 What happens when the research project ends?**

At the end of the project a summary of the results of the project will be available through the researchers at the participant's hospital approximately 6 months after the completion of the study. At the end of the study, the assessor will ask the participant if they would be happy to be contacted after the research ends.

As Etanercept is not an approved treatment for stroke, it will not be available to the participant immediately after completion of the study. The participant should follow their routine care provided by their doctor or allied health professionals.

## **Part 2 How is the research project being conducted?**

### **16 What will happen to information about the participant?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential. For the study, participant information will be identified by a unique identification number and will be stored on a secure electronic data bank at the Florey Institute for Neuroscience and Mental Health. All information collected at the site in relation to this study will be maintained in a locked secure location for a period of 15 years after the completion of the study and will be accessible to the site researchers only. The participant's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about the participant may be obtained from their health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to participation in this research project. The participant's health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, the Florey Institute of Neuroscience and Mental Health, the institution relevant to this Participant Information Sheet, [Name of institution], or as required by law. By signing the Consent Form, you authorise release of, or

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Local governance version [Date] (Site PI use only)

access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the participant's information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## **17 Complaints and Compensation**

If you have any complaints about the research project, you may address these with the person listed under section 20 of this form.

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for the participant. If the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the event of loss or injury, the parties involved in this research project have agreed to cover any medical costs that may be incurred.

## **18 Who is organising and funding the research?**

This research project is being conducted by Professor Vincent Thijs at the Florey Institute of Neuroscience and Mental Health who has been provided funding from the Stroke Foundation to complete the project.

There is no expected financial benefit to the Florey Institute for Neuroscience and Mental Health or any of the involved researchers.

[Name of institution] will receive a payment from the Florey Institute of Neuroscience and Mental Health for undertaking this research project.

No member of the research team will receive a personal payment from the participants involvement in this research project (other than their ordinary wages).

## **19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

## **20 Further information and who to contact**

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Local governance version [Date] (Site PI use only)

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on [Contact phone number] or any of the following people:

**Clinical contact person**

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

For matters relating to research at the site at which the participant is participating, the details of the local site complaints person are:

**Complaints contact person**

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	Austin Health Human Research Ethics Committee
Telephone	03 9496 4090
Email	ethics@austin.org.au

# Consent Form – Person Responsible/ Medical treatment decision maker

<b>Title</b>	A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.
<b>Short Title</b>	Perispinal Etanercept to improve STroke Outcomes (PESTO)
<b>Protocol Number</b>	<i>Version 1 dated 19 July 2019</i>
<b>Project Sponsor</b>	<i>Florey Institute of Neuroscience and Mental Health</i>
<b>Coordinating Principal Investigator/ Principal Investigator</b>	<i>Professor Vincent Thijs /<span style="color: orange;">Principal Investigator</span></i>
<b>Location</b>	<span style="color: orange;">[Location]</span>

## Consent Agreement

I am the Person Responsible/ medical treatment decision maker for [Participant's Name] (the Participant).

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I believe that the participation of the participant in this study is not contrary to their best interests/their preferences and values and their social wellbeing.

I freely agree to the participant participating in this research project as described and understand that I am free to withdraw the participant at any time during the research project without affecting their future health care.

I am aware of my responsibilities as the Person Responsible/ medical treatment decision maker for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [Name of Institution] concerning the participant's disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

**Declaration by Person Responsible/ medical treatment decision maker – for Person Responsible/medical treatment decision maker who has read the information**

Name of Participant (please print) \_\_\_\_\_

Name of Person providing consent (please print) \_\_\_\_\_

Relationship of Person providing consent to Participant \_\_\_\_\_

Signature of Person providing consent \_\_\_\_\_ Date \_\_\_\_\_

**Declaration - for Person Responsible/medical treatment decision maker unable to read the information and consent form**

Witness to the informed consent process

Name (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible/medical treatment decision maker has understood that explanation.

Name of Study Doctor/  
Senior Researcher† (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

# Form for Withdrawal of Participation – Person Responsible/Medical treatment decision maker

**Title** A Prospective multicentre, phase 2b randomised controlled double blind trial, to determine the safety and efficacy of perispinal Etanercept on quality of life at 28 days post treatment.

**Short Title** Perispinal Etanercept to improve STroke Outcomes (PESTO)

**Protocol Number** *Version 1 dated 19 July 2019*

**Project Sponsor** *Florey Institute of Neuroscience and Mental Health*

**Coordinating Principal Investigator/  
Principal Investigator** *Professor Vincent Thijs /Principal Investigator]*

**Location** *[Location]*

## Declaration by Person Responsible/medical treatment decision maker

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant's routine treatment, relationship with those treating them or their relationship with *[Institution]*.

Name of Participant (please print) _____
Name of Person providing consent (please print) _____
Relationship of Person providing consent to Participant _____
Signature of Person providing consent _____ Date _____

Name of Study Doctor/ Senior Researcher (please print) _____
Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.



## ETHICS COMMITTEE CERTIFICATE OF APPROVAL

*This is to certify that*

**Project No:** 275/19

**Project Title:** Early vocational intervention for people who have experienced stroke: A randomised pilot trial

**Principal Researcher:** S 22

**Protocol Version 1.1 dated:** 19-Aug-2019

**Participant Information and Consent Form Version 1.1 dated:** 20-Aug-2019

**Pictorial Consent Form Version 1.0 dated:** 05-Aug-2019

*was considered by the Ethics Committee on **29-Aug-2019**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **02-Sep-2019**.*

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It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

***The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of***

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

***Additionally, the Principal Researcher is required to submit***

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

### SPECIAL CONDITIONS

None

SIGNED:

S 22

Chair, Ethics Committee

*Please quote project number and title in all correspondence*



















## DEED OF NOVATION

This Deed is made between the following parties:

1. LA TROBE UNIVERSITY ABN 64 804 735 113 of Kingsbury Drive and Plenty Road, Bundoora, VIC 3086

(Retiring Party)

AND

2. MONASH UNIVERSITY ABN 12 377 614 012 of Wellington Road, Clayton, VIC, 3800

(Substitute Party)

AND

3. NATIONAL STROKE FOUNDATION ABN 42 006 173 379 of Level 7, 461 Bourke Street, Melbourne, VIC, 3000 ("Stroke Foundation") AND Natasha Lannin of MONASH UNIVERSITY / ALFRED HEALTH (Researcher)

(Continuing Party)

### Background

- A. The Researcher was the successful applicant for and are parties to a document titled "Clinical Trials Conditions of Research Grant Award" dated 28 March 2019 (**the Grant Agreement**) which sets out the terms and conditions upon which the Stroke Foundation has agreed to grant a Return to Life, Return to Work Research Grant (**Research Grant**) to the Researcher. A copy of the Grant Agreement is attached at the Annexure.
- B. The Researcher was the successful applicant for the Research Grant. At the time that she was informed of the decision to grant her the Research Grant, the Researcher was employed by the Retiring Party and therefore the Researcher and the Retiring Party entered into the Grant Agreement, the latter in its capacity as the administering institution. Since that time, the Researcher accepted a new position with the Substitute Party and, as a result, the parties wish to enter into this Deed to formally record the novation of the rights and obligations of the Retiring Party to the Substitute Party on and from the Effective Date.
- C. The Continuing Party has agreed to release and discharge the Retiring Party from its obligations under the Agreement with effect on and from the Effective Date upon the undertaking of the Substitute Party to perform and be bound by the Agreement in place of the Retiring Party on and from the Effective Date.
- D. The Parties agree on and from the Effective Date to novate the Grant Agreement on the terms and conditions of this Deed.

The Parties agree in consideration of the mutual promises contained in this Deed as follows:

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## 1 Definitions and interpretation

### 1.1 Definitions

In this Deed words and phrases defined or referred to in the Grant Agreement have the same meaning when used in this Deed and in addition:

**Business Day** means a day on which banks are open for business in Victoria and which is not a Saturday, Sunday or public holiday;

**Deed** means this deed and all schedules, annexures and attachments;

**Effective Date** means the date on which this Deed is executed by the last party to execute it;

**GST** has the same meaning as in the *A New Tax System (Goods and Services Tax) Act 1999*;

**Power** means any right, power, authority, discretion or remedy conferred on a Party under or by the virtue of this Deed or applicable law; and

**Party** means a party to this Deed.

### 1.2 Interpretation

In this Deed, headings and boldings are for convenience only and do not affect the interpretation of this Deed and, unless the context otherwise requires:

- (a) words importing a gender include any gender;
- (b) words importing the singular include the plural and vice versa;
- (c) headings and clause headings have been inserted for guidance only and shall not be deemed to form any part of the context of this Deed;
- (d) all references to clauses and schedules are to clauses and schedules of this Deed (unless otherwise stated) and includes such clause or schedule as amended or replaced from time to time pursuant to this Deed;
- (e) where any word or phrase has been given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning; and
- (f) an expression importing a natural person includes any company, partnership, joint venture, association, corporation or other body corporate.

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## 2 Novation

### 2.1 Novation

On and from the Effective Date, the Parties novate the Grant Agreement so that:

- (a) the Substitute Party replaces the Retiring Party under the Grant Agreement as if it is an original party to the Grant Agreement; and
- (b) a reference in the Grant Agreement to the Retiring Party must be read as a reference to the Substitute Party.

## 2.2 Assumption of rights and obligations

- (a) Subject to clause 2.2(c) on and from the Effective Date, the Substitute Party:  
must comply with the Grant Agreement as if it had originally been named in the Grant Agreement in place of the Retiring Party; and  
obtains the rights and assumes the obligations and any liability of the Retiring Party under the Grant Agreement.
- (b) On and from the Effective Date, the Continuing Party must comply with the Grant Agreement on the basis that the Substitute Party has replaced the Retiring Party under it in accordance with this Deed.
- (c) The Substitute Party will not be liable for any acts or omissions of the Retiring Party under the Grant Agreement that occurred prior to the Effective Date.

## 2.3 Obligations of Continuing Party

Subject to this Deed, the Continuing Party

- (a) releases and forever discharges the Retiring Party from any of the Retiring Party's obligations or any liability which arose in respect of any act or omission on the part of the Retiring Party under or in respect of the Grant Agreement before the Effective Date; and
- (b) accepts the liability of the Substitute Party in place of the liability of the Retiring Party; and
- (c) will be liable to the Substitute Party for the Continuing Party's obligations or any liability which arose in respect of any act or omission on the part of the Continuing Party under or in respect of the Grant Agreement before the Effective Date.

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## 3 Representations and warranties

### 3.1 General representations and warranties

The Retiring Party and the Substitute Party represent and warrant to the Continuing Party that:

- (a) **authority:** all approvals required in relation to the execution, delivery and performance of this Deed have been obtained and are subsisting;
- (b) **binding obligations:** this Deed constitutes its legal, valid and binding obligations and is enforceable in accordance with its terms;
- (c) **transaction permitted:** the execution, delivery and performance by it of this Deed do not and will not violate:
  - any law, regulation, authorisation, ruling, consent, judgment, order; or
  - its constitution or other constituent documents; and
- (d) **GST (if an Australian resident):** it is registered for GST purposes pursuant to the *A New Tax System (Goods and Services Tax) Act 1999* with the Australian Business Number as specified adjacent to its name on the first page of this Deed.

### 3.2 Survival and repetition

The representations and warranties given in clause 3.1:

- (a) survive the execution of this Deed and the occurrence of the Effective Date; and
- (b) the terms, conditions, matters and circumstances stated in the Grant Agreement are regarded as repeated on the Effective Date.

### 3.3 Independent investigations

The Substitute Party has made and will continue to make independently and without reliance on either the Continuing Party or the Retiring Party, its own investigations into:

- (a) the affairs of the other Parties; and
- (b) the transactions evidenced by the Grant Agreement.

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## 4 Duties, costs and expenses

### 4.1 Costs and expenses

Each Party must pay its own costs and expenses in relation to:

- (a) negotiation, preparation, execution, delivery, completion, variation and discharge of this Deed;
- (b) enforcement, protection or waiver, or attempted enforcement or protection or waiver of any rights under this Deed; and
- (c) giving or obtaining of consent or approval under or in relation to this Deed.

### 4.2 GST

- (a) Unless otherwise indicated, all amounts payable by a Party to another Party in relation to a supply under this Deed have been calculated net of any GST which may be imposed on the supply.
- (b) If GST is imposed on any supply made under this Deed the Party to whom the supply is made (the "recipient") must pay to the Party making the supply (the "supplier") the amount imposed at the same time as and in addition without setoff to the amount the recipient is required to pay the supplier for the supply in question.

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## 5 Notices

- (a) Any notice or other communication including but not limited to any request, demand, consent or approval, to or by a Party to this Deed or the Grant Agreement:

sent to the Continuing Party must be as follows:

**Address:** Occupational Therapy Department, The Alfred, 55 Commercial Road, Melbourne VIC 3004

S 22

sent to the Substitute Party must be as follows:

**Address:** Monash Research Office, Level 1, Chancellery Building D, 26 Sports Walk Clayton Campus, 3800

**Attention:** MRO Directorate - S 22

**Facsimile:** n/a

**Email:** S 22 @monash.edu.au

sent to the Retiring Party must be as follows:

**Address:** La Trobe University, Kingsbury Drive and Plenty Road, Bundoora, VIC 3086

**Attention:** Research Office S 22, Executive Director

**Facsimile:** 03 9479 1464

**Email:** researchgrants@latrobe.edu.au

- (b) Any such notice, request or other communication must be delivered by hand, sent by prepaid post or transmitted electronically or by facsimile, and if it is sent by or transmitted electronically or by facsimile a confirmation copy is to be sent to the recipient by pre-paid post within **2 Business Days** of sending or transmitting the notice electronically or by facsimile.
- (c) A notice, request or other communication will be deemed to be received:
- (1) if delivered by hand, upon delivery;
  - (2) if sent by pre-paid ordinary post within Australia, upon the expiration of 2 Business Days after the date on which it was sent; and
  - (3) if transmitted electronically or by facsimile, upon receipt by the sender of an electronic or facsimile acknowledgment that the communication has been properly transmitted to the recipient.
- (d) A Party may change the address for service of notices by giving written notice of that change to the other Parties.

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## 6 General

### 6.1 Governing law and jurisdiction

- (a) This Deed is governed by the laws of Victoria.
- (b) The Parties irrevocably submit to the exclusive jurisdiction of the Courts of Victoria.
- (c) Each Party irrevocably waives any objection to the venue of any legal process on the basis that the process has been brought in an inconvenient forum.

### 6.2 Prohibition and enforceability

- (a) Any provision of, or the application of any provision of, this Deed or any Power which is prohibited in any jurisdiction is, in that jurisdiction, ineffective only to the extent of that prohibition.
- (b) Any provision of, or the application of any provision of, this Deed which is void, illegal or unenforceable in any jurisdiction does not affect the validity, legality or enforceability of that provision in any other jurisdiction or of the remaining provisions in that or any other jurisdiction.

### **6.3 Waivers**

- (a) The non-exercise of or delay in exercising any power or right of a Party does not operate as a waiver of that power or right, nor does any single exercise of a power or right preclude any other or further exercise of it or the exercise of any other power or right, in relation to a continuing or recurring breach. A power or right may only be waived in writing, signed by the Party to be bound by the waiver executed in the same manner as this Deed;
- (b) To the National Stroke Foundation, Att: Sharon McGowan, Level 7, 461 Bourke St, Melbourne VIC 3000;
- (c) To the Retiring Party, La Trobe University, Research Office, Att: MaryAnne Aitken, Kingsbury Drive and Plenty Road, Bundoora, VIC 3086;
- (d) Neither the Retiring Party nor the Substitute Party by entry into this Deed waive any power or right under the Grant Agreement in relation to any continuing or recurring breach of the Continuing Party.

### **6.4 Variation**

A variation of any term of this Deed must be in writing and signed by the Parties.

### **6.5 Assignment**

This Deed is personal to the Parties and no Party may assign its rights or obligations under this Deed unless mutually agreed by all the Parties.

### **6.6 Further assurances**

Each Party must do all things and execute all further documents necessary to give full effect to this Deed.

### **6.7 Counterparts**

This Deed may be executed electronically and in counterparts. All executed counterparts constitute one document.

### **6.8 To the extent not excluded by law**

The rights, duties and remedies granted or imposed under this Deed operate to the extent not excluded by law.

### **6.9 Attorneys**

If this Deed is executed under a power of attorney, then each of the attorneys executing this Deed states that the attorney has no notice of the revocation of the power of attorney appointing that attorney.

Executed as a Deed: 14 OCTOBER 2019

S 22 Signed sealed and delivered by  
in the presence of:

\_\_\_\_\_  
Signatory

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Natasha Lannin

\_\_\_\_\_  
Name of Witness (please print)

Dated:

Executed as a Deed for and on behalf of  
Monash University pursuant to regulation 76  
of the Monash University (Council) Regulations by:

\_\_\_\_\_  
Authorised Officer

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Halina Oswald

\_\_\_\_\_  
Name of Authorised Officer

\_\_\_\_\_  
Name of Witness (please print)

\_\_\_\_\_  
Director Monash Research Office

\_\_\_\_\_  
Title of Authorised Officer

Dated:

Executed as a Deed for and on behalf of  
LA TROBE UNIVERSITY a body corporate established  
under the La Trobe University Act 2009 by its authorized  
signatory:

S 22

S 22

Director S 22  
Executive Director, Research Office  
La Trobe University  
Bundoora, Victoria 3086

\_\_\_\_\_  
Name (please print)

Dated: 8/10/2019

Director/Secretary signature of  
witness

S 22

\_\_\_\_\_  
Name (please print)  
of witness

Executed by National Stroke Foundation in accordance  
with section 127(1) of the Corporations Act:

S 22

S 22

Director

S 22

\_\_\_\_\_  
Name (please print)

S 22

\_\_\_\_\_  
Name (please print)

Dated: 14/10/2019



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**Executed as a Deed:**

**Signed sealed and delivered by**  
S 22 in the presence of:

\_\_\_\_\_

S 22

S 22

7 | 10 | 2019

S 22

7/10/19  
\_\_\_\_\_  
Signature or Witness  
S 22

\_\_\_\_\_  
Name of Witness (please print)

**Dated:**

**Executed as a Deed for and on behalf of**  
**Monash University pursuant to regulation 76**  
**of the Monash University (Council) Regulations by:**  
S 22

S 22

\_\_\_\_\_  
Authorised Officer

\_\_\_\_\_  
Signature of Witness

S 22

S 22

\_\_\_\_\_  
Name of Authorised Officer

\_\_\_\_\_  
Name of Witness (please print)

**Director Monash Research Office**

\_\_\_\_\_  
Title of Authorised Officer

**Dated:**

**Executed as a Deed for and on behalf of**  
**LA TROBE UNIVERSITY** a body corporate established  
under the *La Trobe University Act 2009* by its authorized  
signatory:

\_\_\_\_\_  
Director

\_\_\_\_\_  
Director/Secretary

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Name (please print)

**Dated:**

**Executed by National Stroke Foundation in accordance  
with section 127(1) of the Corporations Act:**

\_\_\_\_\_  
Director

\_\_\_\_\_  
Director/Secretary

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Name (please print)

**Dated:**























## Medical Research Future Fund – Accelerated Research Initiative Progress Report Assessment

<b>Grantee Name</b>	National Stroke Foundation
<b>Project title</b>	1. <b>S 22</b> 2. "Return to life, return to work" stroke recovery for young survivors
<b>Project number</b>	ARG73055 (MRFF-SF)
<b>Reporting period</b>	01/01/2019 to 31/12/2019
<b>Project risk rating*</b>	Low

### Notes:

This assessment report has a number of purposes which include but are not limited to:

- Providing a basis for making payments
- A record of the review of progress against a grant agreement
- To inform stakeholders on key aspects of the program
- Recordkeeping/AusIndustry due diligence

Information contained in this assessment report, together with the project progress report, may be used in stakeholder reports by the Department of Industry, Innovation and Science and the Department of Health.

All financial information contained within this assessment report, including the grant amount, is GST exclusive.

As per the Ad Hoc Grant Opportunity Service Schedule, default project risk rating is low.



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- Recruitment delays due to a high number of ineligible patients screened, the primary reason cited is due to concurrent enrolment in another clinical trial.

Although the grantee has reported that these issues have been addressed and that they should be able to catch-up, they have requested to extend the final 2 milestone and project end date completion dates by 12 months to the 30<sup>th</sup> June 2022.

AusIndustry has discussed the variation process with the grantee, and recommends delaying a variation until the end of the 2020 reporting period to incorporate any unforeseen issues, or progress made against milestones, this year.

<b>2.3</b>	<b>Have there been any new or unexpected findings/outcomes from the research to date?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
------------	---	---

*Living Guidelines;*

No preliminary findings reported at this early reporting stage.

*Return To Life, Return To Work;*

No preliminary findings reported at this early reporting stage.

### 3. Expenditure

<b>3.1</b>	<b>Does the report indicate that eligible expenditure is broadly in line with the activity budget in the grant agreement?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
------------	---	---

The grantee has advised that expenditure is broadly in line with the activity budget.

<b>3.2</b>	<b>What is the total eligible expenditure for the reporting period?</b>	<b>S 47G</b> (excl GST)
------------	---	-------------------------

<b>3.3</b>	<b>Are there any significant changes to the forecast budget for the remainder of the project?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
------------	---	---

The forecasted project budget is reported to be on track.

### 4. Attachments

<b>4.1</b>	<b>Has the grantee attached any agreed evidence required?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>4.2</b>	<b>Has the grantee attached any published reports or promotional material?</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

The grantee has provided the following listed attachments (see Evidence of Activity doc):

- Letter confirming NHMRC CEO approval of the amended recommendations in the Clinical guidelines for stroke management.
- Stroke Foundation Media Release - Return to Life, Return to Work research grants announced.
- Letter confirming ASTN endorsement of the PESTO trial.
- Austin Health HREC approval of the PESTO trial.
- Austin Health HREC approved Participant Information Sheet/Consent Form for the PESTO trial (Master)
- Austin Health HREC approved Person Responsible Information Sheet/Consent Form for the PESTO trial.
- Alfred Hospital HREC approval for the Return to Work trial.
- Letter confirming ASTN endorsement of the Return to Work trial.
- Alfred Health approved Participant Information Sheet for the Return to Work trial.
- Knowledge Dissemination and Transition Plan for the Return to Work trial.

S 22

12. Return to Work trial registration

### 5. Certification

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5.1	Has the report been certified?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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**6. Risk rating**

6.1	Based on the progress report, what is the project risk rating?	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Medium <input type="checkbox"/> High
<p><i>If medium or high risk, what strategies have been implemented to move the risk rating to an acceptable low risk level?</i></p> <p>Medium – the risk rating for this report is medium due to delays facing the project.</p> <p>The grantee has indicated that a 1 year extension may be required to the project end date (to 30 June 2022) due to the issues discussed in 2.2.</p> <p>AusIndustry recommends assessing the progress reporting due in January 2021 for further progress against milestones. If required, a formal variation can then be processed along with the January 2021 reporting.</p>		

**7. Payment recommendation**

7.1	Based on the progress reporting, is the payment recommended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
S 47G		

**Report Review**

**I have undertaken the assessment of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient's progress report**

CSM name:	S 22
Date:	17/02/2020

**I have verified the review of the Emerging Priorities and Consumer Driven Research/Accelerated Research Program recipient's progress report**

Authorised Officer name:	S 22
Date:	19/02/2020



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## End of Project (Final) Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its final report. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through this report. For varying your grant and grant agreement please refer to the [MRFF Grant Variation Policy](#).

Please ensure that you are using the latest version of this template. You must submit your report on the business.gov.au [portal](#). You can enter the required information in stages and submit when it is complete.

### Project Information

Grant ID	EPCD000019
Grant Opportunity Name	Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation)
Administering Organisation	National Stroke Foundation
Chief Investigator A / Project Lead	S 47G (National Stroke Foundation) S 47G (Return to life PESTO) S 47G (Return to work)
Grant Title	Emerging Priorities and Consumer Driven Research Initiative (July 2018)
Grant Agreement Start and End Dates	23/07/2018 – 30/06/2024
Research Activity Start and End Dates	30/07/2018 – 31/12/2023
Australia New Zealand Clinical Trials Registry Trial ID (where relevant):	'Return to life' - Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976  S 22
Reporting Period	From 30/07/2018 – 31/12/2023
If the Commonwealth Commercialisation Clauses apply to this project, do you plan to execute any new Commercialisation Agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	No

### Project Outcomes

1. Complete the following table for each milestone or objective outlined in the Activity Schedule of your Grant Agreement.

In the comments field, clearly summarise the extent to which you completed all agreed research activities relevant to each milestone/objective and provide a justification for any incomplete milestones/objectives.



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### A. Return to life PESTO

Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
1. Project start date	30/07/2018	30/07/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
3. Successful applicant engaged	31/03/2019	18/03/2019	100%
<b>Comments:</b> As previously reported on 31/01/2023.			



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Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
4. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	28/06/2019	100%
<b>Comments:</b> PESTO - ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration 22/09/2020.			
5. Training of staff at trial sites concludes	31/12/2019	27/10/2020	100%
<b>Comments:</b> PESTO - Austin Health - 27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) - 17/12/2020 & 14&18-01/2021. Alfred Health 09/04/2021.			
6. Approved international trial sites on boarded	31/12/2020	17/12/2020	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
7. Patient recruitment strategy and contingency plans - ongoing until project end	31/12/2021	31/12/2021; 31/12/2022	100%
<p><b>Comments:</b> In total, 126 patients were randomized. Recruitment fell short of the anticipated 168 patients despite multiple efforts to boost recruitment, as discussed in previous reports. Due to the COVID-19 pandemic the project was extended, but further recruitment would have required to additionally extend the project for at least 18 months. A decision was made to stop recruitment with last patient last visit at the end of November 2023.</p> <p>The trial will still deliver on the main outcome. Prior studies have demonstrated a 90% improvement in most post-stroke impairments with perispinal etanercept. In this trial's initial sample size estimation, the research team opted for a highly conservative absolute improvement in quality of life measures. The research team anticipated that a 5 point improvement in SF-36 scores would occur in 30% in the etanercept group and 11% in the placebo group. This absolute difference in improvement with 5 points, 19% (30% minus 11%) is much smaller than the reported 90% improvement in observational studies and one small randomised trial. With 126 patients, the final sample size of PESTO, the trial will have sufficient power to demonstrate a difference of 23% (34% in etanercept group and 11% in the placebo group). This will allow the research team to decide on the efficacy of perispinal etanercept, refute or confirm the nearly universal success of this treatment and deliver a determination to proceed with a definitive phase 3 study.</p>			
8. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
9. Study protocol review by Steering and Ethics Committees – as required	31/12/2022	31/12/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
10. Publication of study protocol and statistical analysis plan	30/06/2023	01/04/2024	90%
<b>Comments:</b> Study protocol manuscript submitted for peer review 25/01/2024 and publication at the European Stroke Journal. Awaiting peer reviewers response. Anticipated end date 01/04/2024. (Refer Attachment 1 – PESTO Study protocol manuscript_Revision 1_submitted for peer review_CONFIDENTIAL)			
11. Patient recruitment concludes	31/12/2023	24/12/2023	100%
<b>Comments:</b> Patient recruitment ended with last patient first visit date on 01/09/2023 in time to finish last follow up on 24/12/2023. In total, 126 patients were randomized. Recruitment fell short of the anticipated 168 patients despite multiple efforts to boost recruitment (as described in point 7).			
12. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2023	30/06/2024	75%



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Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
<p><b>Comments:</b></p> <p><b>Sites</b> Site monitoring is ongoing with an expected end date on 28 March 2024 (New Zealand site closed, Austin site already ended, Alfred site pending minor queries as of 22 March 2024). Delays caused by availability of staff at sites and monitoring personnel (Neuroscience Trials Australia). Final site closeout will occur on 7 April 2024 (Alfred site).</p> <p><b>Results</b> Final results will be analysed after site monitoring, database lock, unblinding. Statistical analysis plan has been finalised and coding completed. In order to maximize recruitment, recruitment period was extended as much as possible towards end of project date. This did not permit closure of sites, analysis of results until after official project end date.</p> <p>Abstract submitted for late breaking presentation at European Stroke Organisation Conference 2024 in Basel, Switzerland, 15-17 May 2024 (refer Attachment 2 - PESTO Abstract submission_ESOC2024_CONFIDENTIAL). <b>The top line trial results will be under embargo until this international presentation. Once the embargo has been lifted the top line results will be shared with Stroke Foundation and the MRFF office.</b></p> <p>The research team aim for final results publication in July 2024 in an international journal (pending acceptance in target journal Lancet Neurology). Upon acceptance the final results will be shared with Stroke Foundation and the MRFF office.</p>			
13. Project end date	31/12/2023	31/12/2023	100%
<p><b>Comments:</b> Official funded activities for the trial have ceased since 31/12/2023 but monitoring, site closeouts and publication/presentation of results will still occur during the first half of 2024 as detailed above.</p>			

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2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above. (min 200, max 300 words)

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2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above (min 200, max 300 words)

**A. Return to life PESTO**

N/A

2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above. (min 200, max 300 words)

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3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines. (min 200, max 300)

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3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines . (min 200, max 300 words)

**A. Return to life PESTO**

PESTO is one of the first randomized trials of pharmacological treatment focussed on stroke recovery in young adults of working age. Inflammation is thought to be one of the mechanisms involved in stroke recovery and as such the PESTO trial is also one of the first to examine inflammatory pathways in stroke in a phase 2b trial. As such PESTO supports research in young stroke recovery, an emerging priority area of unmet need which has the potential to provide new treatments to those suffering from the impact of stroke. If the treatment is successful, this has the potential to affect the large number of Australians who have lifelong consequences of stroke. Given the low cost of etanercept, this is likely to be a cost-effective treatment.

3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines . (min 200, max 300 words)

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4. *Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)*

You should include information about any key enablers or barriers to implementation of your project.

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4. Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)

You should include information about any key enablers or barriers to implementation of your project.

**A. Return to life PESTO**

As of 25 March 2024, the trial results remain unknown. If perispinal etanercept proves to be promising in this phase 2b trial, a definitive phase 3 trial is warranted to conclusively demonstrate the benefits of this treatment. Further grant applications will have to be submitted to gain funding. If perispinal etanercept does not show sufficient promise, this is also important information as it may guide survivors of stroke and health professionals in their decision to undergo this off-label treatment overseas. Future barriers for implementing this treatment if successful, include IP issues as Dr Tobinick holds the rights to this treatment method in an international patent. Additionally, the stroke physician and neurology community will require recommendations for or against this treatment to be included in guidelines. Ideally, converging, robust evidence in two phase 3 trials is generally recommended for new treatments to be adopted by the community at large.

4. Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)

You should include information about any key enablers or barriers to implementation of your project.

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5. *Have you complied with all funding conditions and legislation applicable to the delivery of the project as outlined in the grant agreement? If not, explain why. (max 300 words)*

Yes. This has been ratified by Stroke Foundation and the administering institutions of each project activity.

6. *Complete the following table if your grant involved identifying, supporting and working in partnership with selected organisations to progress their own research project/s. If any of the projects are not completed, explain why.*

This question applies to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
N/A						

## Project Expenditure

7. *Provide details of all expenditure incurred for the project.*

Expenditure should be divided into the same categories as the budget in your grant agreement. The table should indicate for each expenditure item (A), the approved budget (B) and the total



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expenditure: in this period (C), and for the duration of the project (D). The comments field (E) should justify any differences between the budgeted and actual expenditure.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact [mrff@industry.gov.au](mailto:mrff@industry.gov.au).

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8. Provide a statement confirming the eligibility of expenditure incurred for the project. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)

The funds have been expended according to the grant opportunity guidelines. This has been ratified by Stroke Foundation and the administering institutions of each project activity.

9. Provide details of any partner contributions received for the project. Indicate total contributions made per partner for the duration of the project. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.

If a contribution has not been made as expected, describe the impact on the delivery of the Research Activity. If the project did not have partners that committed to make cash or in-kind contributions, enter N/A in the table below.

Name of Partner	Type of Contribution	Expected Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
N/A				

## Project Evaluation

10. Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the [MRFF Monitoring, Evaluation and Learning Strategy \(November 2020\)](#) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were submitted with the application, select N/A in the first row of the table below.

For each Measure of Success applicable to your project:



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- list each outcome/result (one per row), including a quantitative or qualitative description of the target that indicates its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.).
- summarise how you have achieved or completed the target.

Add rows as necessary.

Measure of Success	Outcome/Result	Comments
N/A		

11. *The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has been any media coverage on these outcomes. (min 200, max 300 words)*

Note that your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

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11. *The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has been any media coverage on these outcomes. (min 200, max 300 words)*

#### **A. Return to life PESTO**

As of 25 March 2024, data from PESTO are still being analysed and outcomes will be presented at the European Stroke Organisation Conference (ESOC) in May 2024 and published in July 2024, pending timely acceptance of abstracts and manuscripts. Lay summaries of the findings will be prepared and posted on relevant websites. Stroke Foundation and The Department of Health and Aged Care will be provided the top line results summary at the time of the ESOC 2024 meeting and a full report upon lifting of the embargo by the journal.

11. *The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has*

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12. If the new findings or outcomes will lead or have led to publications, provide information on the status of or plan for the manuscript or publication in the table provided below.

Publication Status	Author(s)	Title	Journal Name/ Preprint Repository	DOI
Published	Coralie English, Kelvin Hill, Dominique A Cadilhac, Maree L Hackett, Natasha A Lannin, Sandy Middleton, Annemarei Ranta, Nigel P Stocks, Julie Davey, Steven G Faux, Erin Godecke and Bruce C V Campbell	Living clinical guidelines for stroke: updates, challenges and opportunities	The Medical Journal of Australia	DOI: 10.5694/mja2.51520
Published	Kelvin Hill, Coralie English, Bruce C V Campbell, Steve McDonald, Loyal Pattuwage, Peta Bates, Chris Lassig, Tari Turner; Living Stroke Guidelines Executive Group and Content Development Group	Feasibility of national living guideline methods: The Australian Stroke Guidelines	Journal of Clinical Epidemiology	DOI: 10.1016/j.jclinepi.2021.11.020
Published	Sophie O'Keefe, Kate Radford, Amanda Farrin, Jodi Oakman, Serena Alves-Stein, Geoffrey G. Cloud, Jacinta Douglas, Mandy Stanley, Natasha A. Lannin	A Tailored Occupational Therapist-Led Vocational Intervention for People With Stroke: Protocol for a Pilot Randomized Controlled Trial.	JMIR Research Protocols	DOI: 10.2196/40548
Published	Nadia Moore, Sandra Reeder, Sophie O'Keefe, Serena Alves-Stein, Emma Schneider, Katelyn Moloney, Kate Radford, Natasha A. Lannin	"I've still got a job to go back to": the importance of early vocational rehabilitation after stroke	Disability and Rehabilitation	DOI: 10.1080/09638288.2023.2230125
Under review	Lucette Lanyon, Ciara Shiggins, Caroline Baker, Serena Alves-	Until you're in the chair and executing your role, you don't	International Journal of Language &	-



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	Stein, Sophie O'Keefe, Emma J. Schneider, Erin Godecke, Kathryn Radford, Natasha A. Lannin	know": Needs and perspectives of people with stroke-related communication disabilities when returning to vocational activity.	Communication Disorders	
In preparation	Natasha A. Lannin, Sophie O'Keefe, Amanda Farrin, Laura Marsden, Serena Alves-Stein, Geoffrey C. Cloud, Mandy Stanley, Laura Jolliffe, Katelyn Moloney, Rebecca Nicks, Katherine Sewell, Nicole Pendrey, Molly Eaton, Tayla Grant, Brittni Nielsen, Laura De Lacy, Kathryn Radford	The Work Trial: Feasibility and acceptance results from an early vocational rehabilitation program for working-age adults after stroke.	Not submitted	-
Under review	Thijs, Cloud, Gilchrist, Parsons, Tilvawala, Ho, Ruthnam, Stanislaus, Sprigg, Walker, Bath, Churilov, Bernhardt	Perispinal Etanercept to improve STroke Outcomes (PESTO): Protocol for a multicenter, international, randomised placebo-controlled trial	European Stroke Journal	-
In preparation	Thijs, Cloud, Gilchrist, Parsons, Tilvawala, Ho, Ruthnam, Stanislaus, Sprigg, Walker, Bath, Churilov, Bernhardt	Perispinal Etanercept to improve STroke Outcomes (PESTO): a multicenter, international, randomised, placebo-controlled phase 2b trial	Lancet Neurology	-

13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform future MRFF funding opportunities. (min 200, max 300 words)

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13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform future MRFF funding opportunities. (min 200, max 300 words)

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13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform future MRFF funding opportunities. (min 200, max 300 words)

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## Updated Business Indicators

14. Provide the following financial data for your organisation for your latest complete financial year.

These fields are mandatory. Entering \$0 is acceptable, if applicable.

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- 
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## Attachments

15. Attach any agreed evidence required to demonstrate successful completion of the project.

Attachment 1 - PESTO Study protocol manuscript\_Revision 1\_submitted for peer review\_CONFIDENTIAL

Attachment 2 - PESTO Abstract submission\_ESOC2024\_CONFIDENTIAL

Attachment 3 - WORK Trial Poster\_SSA\_2023

16. Attach copies of any published reports and promotional material relating to the project.

Links to published publications (as listed in Question 12):

<https://www.mja.com.au/journal/2022/216/10/living-clinical-guidelines-stroke-updates-challenges-and-opportunities>

<https://pubmed.ncbi.nlm.nih.gov/34785347/>

<https://pubmed.ncbi.nlm.nih.gov/36315220/>

<https://www.tandfonline.com/doi/full/10.1080/09638288.2023.2230125>

## Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.

## Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation)

### Independent audit report

#### Background

These templates assist Grantees (and their auditors) to understand the audit requirements under a Commonwealth grant agreement administered by the Department of Industry, Science and Resources. For further information contact us on 13 28 46 or at [business.gov.au](http://business.gov.au).

When an independent audit report is required under our grant agreements the Grantee must provide us with:

- a statement of grant income and expenditure against the expenditure categories under the grant agreement (attachment A)
- an independent audit report on the statement of grant income and expenditure (attachment B)
- certification of certain matters by the auditor (attachment C).

You can find additional information on the grant opportunity relevant to your grant at [business.gov.au](http://business.gov.au) or by calling us on 13 28 46.

#### Eligible expenditure

Advice on eligible expenditure for projects under the grant opportunity can be found in grant opportunity guidelines. These guidelines are revised from time to time and therefore more than one version of the document may exist. The relevant guidelines are those that were effective at the time the Grantee's application was accepted.

It is essential that Grantees and their auditors understand the eligible expenditure requirements because these determine whether, and the extent to which, certain costs are reportable and claimable.

The amount of grant funding we approve is based on the Grantee's estimated eligible expenditure, as provided in their application. However, the grant funding any Grantee is ultimately entitled to receive is determined against actual eligible expenditure incurred and paid for on the project. The grant amount specified in the grant agreement is the **maximum** amount the Grantee may be paid.

The expenditure reported in the 'statement of grant income and expenditure' at attachment A must represent actual 'eligible expenditure' paid on the project during that period.

## Attachment A – Statement of grant income and expenditure

Grant opportunity name	Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation)
Project number	EPCD000019
Grantee	National Stroke Foundation
Project title	Emerging Priorities and Consumer Driven Research Initiative (July 2018)
Reporting period start date	30 July 2018 [project start date]
Reporting period end date	31 December 2023 [period end date]

This statement of grant income and expenditure must be prepared by the Grantee and contain the following:

- Statement of funds, Grantee contributions and other financial assistance\*
- Statement of eligible expenditure\*
- Notes to the statement of eligible expenditure, explaining the basis of compilation
- Certification by directors of the Grantee
- \*We will compare this information to that detailed in the grant agreement.

#### 1. Statement of funds, Grantee contributions and other financial assistance

Complete the following table for all cash [and in-kind] contributions for your project for the period in question, including

- the grant
- other government funding
- your own contributions
- partner or other third party contributions
- any additional private sector funding.

Insert rows as required.

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### 3. Note to the statement of eligible expenditure

#### 3.1 Eligible expenditure

The eligible expenditure as reported in the statement of eligible expenditure is in accordance with the grant opportunity guidelines.

#### 3.2 Basis of compilation

This statement of eligible expenditure has been prepared to meet the requirements of the grant agreement between National Stroke Foundation and the Commonwealth represented by the Department of Health and Aged Care. Significant accounting policies applied in the compilation of the statement of grant income and expenditure include the following:

[enter details]

#### 4. Certification by directors [if not director, replace with appropriate equivalent]

Grantee name: National Stroke Foundation

Project number: EPCD000019

For the period 30/07/2018 to 31/12/2023

We confirm that, to the best of our knowledge and believe, having made such enquiries as we considered necessary for the purpose of appropriately informing ourselves:

##### Statement of grant income and expenditure

- a. We have fulfilled our responsibilities for the preparation of the statement of grant income and expenditure in accordance with the [cash/accrual] basis of accounting and the terms of the grant agreement with the Commonwealth, represented by the Department of Health and Aged Care dated 23 July 2018; in particular, the statement of grant income and expenditure presents fairly in accordance therewith.
- b. All events subsequent to the date of the statement of grant income and expenditure which require adjustment or disclosure so as to present fairly the statement of grant income and expenditure, have been adjusted or disclosed.
- c. [Where applicable] The effects of uncorrected misstatements are immaterial, both individually and in the aggregate, to the statement of grant income and expenditure as a whole. A list of the uncorrected misstatements is attached to this representation letter.
- d. That all Grantee contributions and other financial assistance were spent for the purpose of the project and in accordance with the grant agreement and that the Grantee has complied with the grant agreement and relevant accounting policies.
- e. That salaries and allowances paid to persons involved in the project are in accordance with any applicable award or agreement in force under any relevant law on industrial or workplace relations.

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Signature .. ...

Name

Director

Date 28/03/2024

S 22

Signature

Name

Director

Date 28/03/2024

5. For Auditor use only

I certify that this statement of grant income and expenditure is the one used to prepare my independent audit report dated 28 March 2024 for the Department of Industry, Science and Resources.

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Signature .....

Name

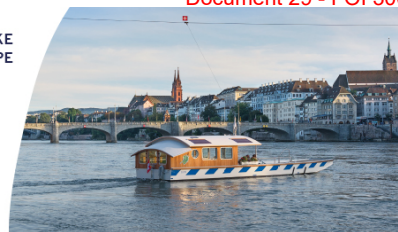
Position Partner

Auditor's employer PITCHER PARTNERS

Date 28/03/2024

## 10<sup>th</sup> European Stroke Organisation Conference

15-17 May 2024, Basel, Switzerland



### Abstract N°: 1250

**Track:** PLACEHOLDER Late Breaking Trials  
**Category:** 2.04 PLACEHOLDER - Rehabilitation & recovery

**Title:** A MULTICENTRE, RANDOMISED PLACEBO-CONTROLLED TRIAL, TO DETERMINE SAFETY AND EFFICACY OF PERISPINAL ETANERCEPT ON QUALITY OF LIFE

**Vincent Thijs**\*<sup>1,2,3</sup>, **Geoffrey Cloud**<sup>4,5</sup>, **Nigel Gilchrist**<sup>6</sup>, **Brooke Parsons**<sup>1</sup>, **Jan Ho**<sup>1</sup>, **Nikola Sprigg**<sup>7,8</sup>, **Marion Walker**<sup>7</sup>, **Philip Bath**<sup>7,8</sup>, **Leonid Churilov**<sup>2</sup>, **Julie Bernhardt**<sup>1</sup>

<sup>1</sup>Florey Institute of Neuroscience and Mental Health, Stroke, Heidelberg, Australia, <sup>2</sup>University of Melbourne, Melbourne, Australia, <sup>3</sup>Austin Health, Department of Neurology, Heidelberg, Australia, <sup>4</sup>Alfred Health, Melbourne, Australia, <sup>5</sup>Monash University, Department of Neuroscience, Central Clinical School, Melbourne, Australia, <sup>6</sup>CGM Research Institute, Christchurch, New Zealand, <sup>7</sup>University of Nottingham, Nottingham, UK, Stroke Trials Unit, Mental Health & Clinical Neuroscience, Nottingham, United Kingdom, <sup>8</sup>Nottingham university Hospitals NHS Trust, Stroke, Nottingham, United Kingdom

**Background and aims:** A large proportion of stroke survivors will have long-lasting, debilitating neurological impairments, yet few efficacious medical treatment options are available. Etanercept inhibits binding of tumour necrosis factor to its receptor and is used in the treatment of inflammatory conditions. Perispinal subcutaneous injection followed by a supine, head down position may bypass the blood brain barrier. In observational studies and one small randomised controlled trial the majority of patients showed improvement in multiple post-stroke impairments. Perispinal Etanercept to improve STroke Outcomes (PESTO) investigates whether perispinal subcutaneous injection of etanercept improves quality of life and is safe in patients with chronic, disabling, effects of stroke.

**Methods:** PESTO is a phase 2b, international, randomised placebo-controlled trial. Adult participants with a history of stroke between 1 and 15 years before enrolment and a current modified Rankin scale between 2 and 5 who are otherwise eligible for etanercept are randomised 1:1 to single dose injection of etanercept or placebo. The primary efficacy outcome is quality of life as measured using the Short Form 36 Health Inventory at day 28 after first injection. The sample size target is a total of 168 participants assuming an improvement of the SF-36 in 11% of participants in the control arm and in 30% of participants in the intervention arm, 80% power and 5% alpha.

**Results:** Recruitment and outcome measurements are completed, and final results will be presented.

**Conclusions:** PESTO aims to provide level 1 evidence on the safety and efficacy of perispinal etanercept in patients with long-term disabling effects of stroke.

**On behalf of:** PESTO investigators

Confidential



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27 March 2024

## INDEPENDENT AUDITOR'S REPORT TO MANAGEMENT

We have audited the statement of grant income and expenditure "the financial statement" of National Stroke Foundation "the Recipient" in respect of Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation) "the Grant" from the Department of Health, "the Grant Provider", for the period 30/07/2018 to 31/12/2023.

In our opinion the financial statement is properly drawn up in accordance with the grant agreement between National Stroke Foundation and the Commonwealth and presents fairly in all material respects the presentation of the income and expenditure of the recipient in respect of the Grant for the period 30/07/2018 to 31/12/2023 based on the accruals basis of accounting.

### *Basis for Opinion*

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statement section of our report. We are independent of the Company in accordance with the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (including Independence Standards) "the Code" that are relevant to our audit of the financial statement in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### *Responsibilities of Management for the Financial Statement*

Management is responsible for the preparation and fair presentation of the financial statement in accordance with the basis of accounting; this includes determining that the basis of accounting is an acceptable basis for the preparation of the financial statement in accordance with the Grant terms between the Grant Provider and the Recipient, and for such internal control as the management determines is necessary to enable the preparation of a financial statement that is free from material misstatement, whether due to fraud or error.

Adelaide Brisbane Melbourne Newcastle Perth Sydney

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S SCHONBERG	T SAKELL	A E CLERICI	A M KOKKINOS	A T CLUGSTON	K J DAVIDSON	M J WILSON	T L ARTHORNE	D BURT	S CRAIG
S DAHN	G I NORISKIN	D J HONEY	P B BRAINE	S J DALL	D R DOHERTY	I CULL	Y TANG	L BAINBRIDGE	1 MALCOLM
P A TISE	A T DAVIDSON	G J NELSEN	G A DEBONO	M G JOZWIK					



### *Auditor's Responsibilities for the Audit of the Financial Statement*

Our objectives are to obtain reasonable assurance about whether the amounts in the financial statement as a whole are free from material misstatement in the calculation, apportionment and presentation of the expenditure, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial statement.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statement, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Recipient's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Evaluate the overall presentation, structure and content of the financial statement, and whether the financial statement represents the underlying transactions and events in a manner that achieves fair presentation.

We communicate with management regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control relevant to the Grant that we identify during our audit.

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Partner

PITCHER PARTNERS

Melbourne

Date: 27 March 2024





































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## End of Project (Final) Report

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its final report. The Department of Health and Aged Care (the Department) reserves the right to amend or adjust the requirements.

Variations should not be requested through this report. For varying your grant and grant agreement please refer to the [MRFF Grant Variation Policy](#).

Please ensure that you are using the latest version of this template. You must submit your report on the business.gov.au [portal](#). You can enter the required information in stages and submit when it is complete.

### Project Information

Grant ID	EPCD000019
Grant Opportunity Name	Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation)
Administering Organisation	National Stroke Foundation
Chief Investigator A / Project Lead	Dr Lisa Murphy (National Stroke Foundation) Professor Vincent Thijs (Return to life PESTO) Professor Natasha Lannin (Return to work)
Grant Title	Emerging Priorities and Consumer Driven Research Initiative (July 2018)
Grant Agreement Start and End Dates	23/07/2018 – 30/06/2024
Research Activity Start and End Dates	30/07/2018 – 31/12/2023
Australia New Zealand Clinical Trials Registry Trial ID (where relevant):	'Return to life' - Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976  S 22
Reporting Period	From 30/07/2018 – 31/12/2023
If the Commonwealth Commercialisation Clauses apply to this project, do you plan to execute any new Commercialisation Agreements that relate to Relevant Intellectual Property developed during the term of the Grant?	No

### Project Outcomes

1. Complete the following table for each milestone or objective outlined in the Activity Schedule of your Grant Agreement.

In the comments field, clearly summarise the extent to which you completed all agreed research activities relevant to each milestone/objective and provide a justification for any incomplete milestones/objectives.



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### A. Return to life PESTO

Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
1. Project start date	30/07/2018	30/07/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
3. Successful applicant engaged	31/03/2019	18/03/2019	100%
<b>Comments:</b> As previously reported on 31/01/2023.			



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Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
4. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	28/06/2019	100%
<b>Comments:</b> PESTO - ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration 22/09/2020.			
5. Training of staff at trial sites concludes	31/12/2019	27/10/2020	100%
<b>Comments:</b> PESTO - Austin Health - 27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) - 17/12/2020 & 14&18-01/2021. Alfred Health 09/04/2021.			
6. Approved international trial sites on boarded	31/12/2020	17/12/2020	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
7. Patient recruitment strategy and contingency plans - ongoing until project end	31/12/2021	31/12/2021; 31/12/2022	100%
<p><b>Comments:</b> In total, 126 patients were randomized. Recruitment fell short of the anticipated 168 patients despite multiple efforts to boost recruitment, as discussed in previous reports. Due to the COVID-19 pandemic the project was extended, but further recruitment would have required to additionally extend the project for at least 18 months. A decision was made to stop recruitment with last patient last visit at the end of November 2023.</p> <p>The trial will still deliver on the main outcome. Prior studies have demonstrated a 90% improvement in most post-stroke impairments with perispinal etanercept. In this trial's initial sample size estimation, the research team opted for a highly conservative absolute improvement in quality of life measures. The research team anticipated that a 5 point improvement in SF-36 scores would occur in 30% in the etanercept group and 11% in the placebo group. This absolute difference in improvement with 5 points, 19% (30% minus 11%) is much smaller than the reported 90% improvement in observational studies and one small randomised trial. With 126 patients, the final sample size of PESTO, the trial will have sufficient power to demonstrate a difference of 23% (34% in etanercept group and 11% in the placebo group). This will allow the research team to decide on the efficacy of perispinal etanercept, refute or confirm the nearly universal success of this treatment and deliver a determination to proceed with a definitive phase 3 study.</p>			

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8. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
9. Study protocol review by Steering and Ethics Committees – as required	31/12/2022	31/12/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
10. Publication of study protocol and statistical analysis plan	30/06/2023	01/04/2024	100%
<p><b>Comments:</b> Study protocol manuscript submitted for peer review 25/01/2024 and publication at the European Stroke Journal. Awaiting peer reviewers response. Anticipated end date 01/04/2024. (Refer Attachment 1 – PESTO Study protocol manuscript_Revision 1_submitted for peer review_CONFIDENTIAL)</p> <p><b>Update 9 July 2024:</b> Study protocol manuscript published in European Stroke Journal 27/04/2024 (<a href="https://doi.org/10.1177/23969873241249248">https://doi.org/10.1177/23969873241249248</a>). Statistical analysis plan finalised and will be included in final publication.</p>			
11. Patient recruitment concludes	31/12/2023	24/12/2023	100%



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Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
<b>Comments:</b> Patient recruitment ended with last patient first visit date on 01/09/2023 in time to finish last follow up on 24/12/2023. In total, 126 patients were randomized. Recruitment fell short of the anticipated 168 patients despite multiple efforts to boost recruitment (as described in point 7).			
12. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2023	30/06/2024	100%
<p><b>Comments:</b></p> <p><b>Sites</b> Site monitoring is ongoing with an expected end date on 28 March 2024 (New Zealand site closed, Austin site already ended, Alfred site pending minor queries as of 22 March 2024). Delays caused by availability of staff at sites and monitoring personnel (Neuroscience Trials Australia). Final site closeout will occur on 7 April 2024 (Alfred site).</p> <p><b>Update 9 July 2024:</b> All sites have been closed.</p> <p><b>Results</b> Final results will be analysed after site monitoring, database lock, unblinding. Statistical analysis plan has been finalised and coding completed. In order to maximize recruitment, recruitment period was extended as much as possible towards end of project date. This did not permit closure of sites, analysis of results until after official project end date.</p> <p>Abstract submitted for late breaking presentation at European Stroke Organisation Conference 2024 in Basel, Switzerland, 15-17 May 2024 (refer Attachment 2 - PESTO Abstract submission_ESOC2024_CONFIDENTIAL). The top line trial results will be under embargo until this international presentation. Once the embargo has been lifted the top line results will be shared with Stroke Foundation and the MRFF office.</p> <p><b>Update 9 July 2024:</b> Abstract accepted for late breaking presentation at European Stroke Organisation Conference 2024 in Basel, Switzerland. Results presented on 15 May 2024 with <a href="#">press release</a> by the European Stroke Organisation Conference.</p> <p>The research team aim for final results publication in July 2024 in an international journal (pending acceptance in target journal Lancet Neurology). Upon acceptance the final results will be shared with Stroke Foundation and the MRFF office.</p> <p><b>Update 9 July 2024:</b> Journal article drafted, will be circulated for co-author comments, planned submission to Lancet Neurology, 30 July 2024.</p>			
13. Project end date	31/12/2023	31/12/2023	100%
<b>Comments:</b> Official funded activities for the trial have ceased since 31/12/2023 but monitoring, site closeouts and publication/presentation of results will still occur during the first half of 2024 as detailed above.			

## B. Return to work

Milestone/Objective – B. Return to work	Agreed End Date	Actual/Anticipated End Date	Current % Complete
1. Project start date	30/07/2018	30/07/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
3. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	06/11/2018	100%
<b>Comments:</b> Trial registration 20/08/2019; ethics 2/09/2019; ASTN 06/11/2019			
4. Training of staff at trial sites concludes	31/12/2019	30/11/2019	100%
<b>Comments:</b> As previously reported on 29/07/2022.			



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Milestone/Objective – B. Return to work	Agreed End Date	Actual/Anticipated End Date	Current % Complete
5. Publication of study protocol and statistical analysis plan	31/12/2022	Submitted 30/4/22 Preprints 28/06/2022 Published 31/10/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
6. Patient recruitment concludes	30/04/2022	30/04/2022	100%
<b>Comments:</b> As previously reported on 31/01/2023.			
7. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%
<b>Comments:</b> As previously reported on 29/07/2022.			
8. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2022	Close out: 31/12/2022 Publication plan: 24/12/2022	100%
<b>Comments:</b> Outcome data for all participants has been collected, with participant recruitment also concluded. Analysis of results has been completed with data analysis complete, publication manuscript in progress.			
9. Project end date	31/12/2022	31/12/2022	100%
<b>Comments:</b> Project complete.			

2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above. (min 200, max 300 words)

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2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above (min 200, max 300 words)

**A. Return to life PESTO**

N/A

2. Describe the extent to which you completed any additional research activities undertaken during the reporting period that are not captured in the table above. (min 200, max 300 words)

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S 22

3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines. (min 200, max 300 words)

S 22

3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines . (min 200, max 300 words)

**A. Return to life PESTO**

PESTO is one of the first randomized trials of pharmacological treatment focussed on stroke recovery in young adults of working age. Inflammation is thought to be one of the mechanisms involved in stroke recovery and as such the PESTO trial is also one of the first to examine inflammatory pathways in stroke in a phase 2b trial. As such PESTO supports research in young stroke recovery, an emerging priority area of unmet need which has the potential to provide new treatments to those suffering from the impact of stroke. If the treatment is successful, this has the potential to affect the large number of Australians who have lifelong consequences of stroke. Given the low cost of etanercept, this is likely to be a cost-effective treatment.

**Update 9 July 2024:**

Based on the primary findings of the trial, the research team found no evidence that perispinal etanercept is an effective treatment for chronic stroke. This is important information for the community living with stroke and for health professionals in providing evidence-based recommendations.

3. Provide a statement explaining how you have met the objectives and intended outcomes of the project as specified in section 1.3 of the grant opportunity guidelines . (min 200, max 300 words)

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4. *Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)*

You should include information about any key enablers or barriers to implementation of your project.

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4. Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)

You should include information about any key enablers or barriers to implementation of your project.

#### **A. Return to life PESTO**

As of 25 March 2024, the trial results remain unknown. If perispinal etanercept proves to be promising in this phase 2b trial, a definitive phase 3 trial is warranted to conclusively demonstrate the benefits of this treatment. Further grant applications will have to be submitted to gain funding. If perispinal etanercept does not show sufficient promise, this is also important information as it may guide survivors of stroke and health professionals in their decision to undergo this off-label treatment overseas. Future barriers for implementing this treatment if successful, include IP issues as Dr Tobinick holds the rights to this treatment method in an international patent. Additionally, the stroke physician and neurology community will require recommendations for or against this treatment to be included in guidelines. Ideally, converging, robust evidence in two phase 3 trials is generally recommended for new treatments to be adopted by the community at large.

#### **Update 9 July 2024:**

PESTO has found no evidence to support administration of perispinal etanercept compared to placebo injection. The findings do not support further development of a clinical trial program of etanercept in chronic stroke, using the broad inclusion criteria of PESTO. The findings are relevant as they will guide survivors of stroke and health professionals in their decision to undergo this off-label treatment overseas. They will also help other researchers in planning future trials of anti-inflammatory agents after stroke. We anticipate that stroke guidelines will advise against this treatment due to lack of robust clinical evidence and no benefit over placebo treatment.

4. Provide a summary of how you are implementing your research findings and ensuring their translation to support improved health outcomes. (min 200, max 300 words)



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You should include information about any key enablers or barriers to implementation of your project.

#### **Trial Outcome 1: Acceptability**

Preliminary Result:

- Process evaluation findings suggest control intervention was not acceptable.  
For scale-up: Perceived lack of equipoise may hinder recruitment; switch to non-traditional trial design (TWiC) for next trial to ensure consumer choice, and improve translation.
- Planned RCT outcomes deemed important to stakeholders.  
For scale-up: Continue with highly-valued outcomes as primary outcome in future trial.

#### **Trial Outcome 2: Adoption**

Preliminary Result:

- Recruitment issues during COVID-19 pandemic.
- Recruitment of adults with post-stroke communication disability (20% of sample).  
For scale-up: Successful use of pictorial consent.

#### **Trial Outcome 3: Appropriateness**

Preliminary Result:

- Intervention perceived as excellent fit.
- Recommendations to adapt inclusion criteria (time post-stroke).  
For scale-up: Increase upper limit of time post-stroke.
- Recommendations to include elements (driving, cognitive-communication, mood disorders).  
For scale-up: Develop module for mood and vocational rehabilitation, cognitive-communication deficits, community transport.

#### **Trial Outcome 4: Feasibility**

Preliminary Result:

- Study protocol perceived to be complex / multifaceted, but feasible.  
For scale-up: Include structured clinician training to maximise likelihood of successful RCT.
- Transition to telehealth (during COVID-19) was feasible and acceptable.

#### **Trial Outcome 5: Fidelity**

Preliminary Result:

- High adherence to pilot intervention.  
For scale-up: Anticipate successful testing of intervention effectiveness in powered trial – now funded.

#### **Trial Outcome 6: Penetration**

Preliminary Result:

- High levels of screening, with excellent levels of eligibility and consent rates.  
For scale-up: Continue to use consistent recruitment strategies in future Young Stroke trials.

5. *Have you complied with all funding conditions and legislation applicable to the delivery of the project as outlined in the grant agreement? If not, explain why. (max 300 words)*



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Yes. This has been ratified by Stroke Foundation and the administering institutions of each project activity.

6. Complete the following table if your grant involved identifying, supporting and working in partnership with selected organisations to progress their own research project/s. If any of the projects are not completed, explain why.

This question applies to grants where the funded organisation is responsible for supporting research projects led by other organisations. If your grant did not involve this type of arrangement, enter N/A in the table below.

Subcontractor/ Awardee	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided (AUD)	Start Date of Project	% Project Complete
N/A						

## Project Expenditure

7. Provide details of all expenditure incurred for the project.

Expenditure should be divided into the same categories as the budget in your grant agreement. The table should indicate for each expenditure item (A), the approved budget (B) and the total expenditure: in this period (C), and for the duration of the project (D). The comments field (E) should justify any differences between the budgeted and actual expenditure.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or if you have any questions about expenditure your administration officer or Project Lead should contact [mrff@industry.gov.au](mailto:mrff@industry.gov.au).

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8. Provide a statement confirming the eligibility of expenditure incurred for the project. If grant funds have been used to cover costs for ineligible items, provide details of those costs and explain why they have been incurred. (max 300 words)

The funds have been expended according to the grant opportunity guidelines. This has been ratified by Stroke Foundation and the administering institutions of each project activity.



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9. Provide details of any partner contributions received for the project. Indicate total contributions made per partner for the duration of the project. This table must be completed if the project partners are making a cash or in-kind contribution that is essential to the project.

If a contribution has not been made as expected, describe the impact on the delivery of the Research Activity. If the project did not have partners that committed to make cash or in-kind contributions, enter N/A in the table below.

Name of Partner	Type of Contribution	Expected Value of Contribution (AUD)	Actual Value of Contribution (AUD)	Comments
N/A				

## Project Evaluation

10. Complete the following table for each outcome or result against which your contribution to the MRFF Measures of Success is being evaluated. Refer to the [MRFF Monitoring, Evaluation and Learning Strategy \(November 2020\)](#) for more information. A response is mandatory if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. If no Measures of Success were submitted with the application, select N/A in the first row of the table below.

For each Measure of Success applicable to your project:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that indicates its achievement or completion (Note: You may select the same Measure of Success for several outcomes/results.).
- summarise how you have achieved or completed the target.

Add rows as necessary.

Measure of Success	Outcome/Result	Comments
N/A		

11. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has been any media coverage on these outcomes. (min 200, max 300 words)

Note that your response may be used in public communications about the MRFF, and that you may be contacted to expand on your response below. Please indicate whether any of the information you provide is commercial in confidence.

S 22



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Department of Health and Aged Care

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Future Fund



11. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has been any media coverage on these outcomes. (min 200, max 300 words)

#### **A. Return to life PESTO**

As of 25 March 2024, data from PESTO are still being analysed and outcomes will be presented at the European Stroke Organisation Conference (ESOC) in May 2024 and published in July 2024, pending timely acceptance of abstracts and manuscripts. Lay summaries of the findings will be prepared and posted on relevant websites. Stroke Foundation and The Department of Health and Aged Care will be provided the top line results summary at the time of the ESOC 2024 meeting and a full report upon lifting of the embargo by the journal.

#### **Update 9 July 2024:**

On 15 May 2024 there was a [press release](#) describing the top line results of the trial by the European Stroke Organisation Conference.

This was picked up and published by the online medical journal 'Medical Dialogues':

<https://medicaldialogues.in/neurology-neurosurgery/news/perispinal-administration-of-etanercept-may-not-improve-quality-of-life-in-chronic-stroke-patients-claims-research-129159>.

Stroke Foundation and The Department of Health and Aged Care will be advised upon lifting of the embargo by the journal in which the final results will be published.

11. The Department would like to publicise findings from this research. Using lay language, explain in a few sentences what are the most important finding(s) or outcome(s) from your project, and why they are important. Include any new or unexpected findings or outcomes. Indicate if there has been any media coverage on these outcomes. (min 200, max 300 words)

S 22

12. If the new findings or outcomes will lead or have led to publications, provide information on the status of or plan for the manuscript or publication in the table provided below.

Publication Status	Author(s)	Title	Journal Name/ Preprint Repository	DOI
Published	Coralie English, Kelvin Hill, Dominique A Cadilhac, Maree L Hackett,	Living clinical guidelines for stroke: updates, challenges and opportunities	The Medical Journal of Australia	DOI: 10.5694/mja2.51520


**Australian Government**
**Department of Health and Aged Care**

	Natasha A Lannin, Sandy Middleton, Annemarei Ranta, Nigel P Stocks, Julie Davey, Steven G Faux, Erin Godecke and Bruce C V Campbell			
Published	Kelvin Hill, Coralie English, Bruce C V Campbell, Steve McDonald, Loyal Pattuwage, Peta Bates, Chris Lassig, Tari Turner; Living Stroke Guidelines Executive Group and Content Development Group	Feasibility of national living guideline methods: The Australian Stroke Guidelines	Journal of Clinical Epidemiology	DOI: 10.1016/j.jclinepi.2021.11.020
Published	Sophie O'Keefe, Kate Radford, Amanda Farrin, Jodi Oakman, Serena Alves-Stein, Geoffrey G. Cloud, Jacinta Douglas, Mandy Stanley, Natasha A. Lannin	A Tailored Occupational Therapist-Led Vocational Intervention for People With Stroke: Protocol for a Pilot Randomized Controlled Trial.	JMIR Research Protocols	DOI: 10.2196/40548
Published	Nadia Moore, Sandra Reeder, Sophie O'Keefe, Serena Alves-Stein, Emma Schneider, Katelyn Moloney, Kate Radford, Natasha A. Lannin	"I've still got a job to go back to": the importance of early vocational rehabilitation after stroke	Disability and Rehabilitation	DOI: 10.1080/09638288.2023.2230125
Under review	Lucette Lanyon, Ciara Shiggins, Caroline Baker, Serena Alves-Stein, Sophie O'Keefe, Emma J. Schneider, Erin Godecke, Kathryn Radford, Natasha A. Lannin	Until you're in the chair and executing your role, you don't know": Needs and perspectives of people with stroke-related communication disabilities when returning to vocational activity.	International Journal of Language & Communication Disorders	-


**Australian Government**
**Department of Health and Aged Care**

In preparation	Natasha A. Lannin, Sophie O'Keefe, Amanda Farrin, Laura Marsden, Serena Alves-Stein, Geoffrey C. Cloud, Mandy Stanley, Laura Jolliffe, Katelyn Moloney, Rebecca Nicks, Katherine Sewell, Nicole Pendrey, Molly Eaton, Tayla Grant, Brittni Nielsen, Laura De Lacy, Kathryn Radford	The Work Trial: Feasibility and acceptance results from an early vocational rehabilitation program for working-age adults after stroke.	Not submitted	-
Published	Thijs, Cloud, Gilchrist, Parsons, Tilvawala, Ho, Ruthnam, Stanislaus, Sprigg, Walker, Bath, Churilov, Bernhardt	Perispinal Etanercept to improve STroke Outcomes (PESTO): Protocol for a multicenter, international, randomised placebo-controlled trial	European Stroke Journal	<a href="https://doi.org/10.1177/23969873241249248">https://doi.org/10.1177/23969873241249248</a>
In preparation	Thijs, Cloud, Gilchrist, Parsons, Tilvawala, Ho, Ruthnam, Stanislaus, Sprigg, Walker, Bath, Churilov, Bernhardt	Perispinal Etanercept to improve STroke Outcomes (PESTO): a multicenter, international, randomised, placebo-controlled phase 2b trial	Lancet Neurology	-

13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform future MRFF funding opportunities. (min 200. max 300 words)

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S 22

13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform future MRFF funding opportunities. (min 200, max 300 words)

#### **A. Return to life PESTO**

As the COVID-19 pandemic severely impacted recruitment, pandemic contingency plans should be included in further trial plans including telehealth, remote dispensation of pharmaceutical products and other treatments.

Recruitment for this trial was hampered by having only 3 sites in Australia and New Zealand which limited participation due to high travel and accommodation costs especially during the pandemic. Given the ability to travel for survivors of stroke is also limited in general, greater proximity of recruitment sites would have been helpful. Although this was attempted, many sites did not have capacity to additionally run this trial. Recruitment could have been facilitated by increasing the number of recruiting sites overseas (which was originally planned but due to COVID-19 the UK did not participate in this trial).

13. Describe any barriers to translation or implementation of research you have faced that may systemically affect the broader sector, discipline or field. This information will be used to inform

S 22

## Updated Business Indicators

14. Provide the following financial data for your organisation for your latest complete financial year.

These fields are mandatory. Entering \$0 is acceptable, if applicable.

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## Attachments

15. Attach any agreed evidence required to demonstrate successful completion of the project.

Attachment 1 - PESTO Study protocol manuscript\_Revision 1\_submitted for peer review\_CONFIDENTIAL

Attachment 2 - PESTO Abstract submission\_ESOC2024\_CONFIDENTIAL

Attachment 3 - WORK Trial Poster\_SSA\_2023

16. Attach copies of any published reports and promotional material relating to the project.

Links to published publications (as listed in Question 12):

<https://www.mja.com.au/journal/2022/216/10/living-clinical-guidelines-stroke-updates-challenges-and-opportunities>

<https://pubmed.ncbi.nlm.nih.gov/34785347/>

<https://pubmed.ncbi.nlm.nih.gov/36315220/>

<https://www.tandfonline.com/doi/full/10.1080/09638288.2023.2230125>

<https://journals.sagepub.com/doi/full/10.1177/23969873241249248>

## Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with the relevant grant opportunity guidelines, as well as all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.
- you are aware that the grant agreement empowers the Department to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.



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## Medical Research Future Fund Progress and Final Report Checklist

<b>Grant ID</b>	EPCD000019
<b>Lead Chief Investigator</b>	S 22 (National Stroke Foundation) S 22 (Return to life PESTO) S 22 (Return to work)
<b>Institution/Organisation</b>	National Stroke Foundation
<b>Grant Title</b>	S 22 t and Return to life, S 22
<b>Grant Opportunity</b>	Accelerated Research Program
<b>Report Due Date</b>	31/01/2023
<b>Report Period</b>	01/01/2022 – 31/12/2022
<b>Date Report Provided to BGH</b>	31/01/2023
<b>ANZCTR Trial ID</b>	[where relevant]
<b>Total Value of Grant</b>	\$2,500,000
<b>Value of Payments to date</b>	\$2,500,000
<b>Report Linked to a Payment?</b>	No
<b>Next Payment Due Date</b>	Nil
<b>Next Payment Amount</b>	Nil
<b>Previous Risk Rating</b>	Low

The following information has been supplied by the grantee and is being provided to the Department of Health and Aged Care to inform its review of grant progress and/or completion:

Attachment Name	Description
MRFF BGH Progress Report 31.01.2023	Progress Report 31.01.2023
EPCD000019 National Stroke Foundation Variation Contract Executed 28 October 2022	Executed Variation

In alignment with the reporting requirements for MRFF grants, I can confirm that the report provided has been quality checked against the following: (tick each box to confirm completion; if unable to tick, note in comments where not applicable or where followed-up with Grantee, and also provide further requested information to Health)

<b>Project Information</b>	Project information such as Grant ID, title, institutional/ organisational details are correctly filled out. <input checked="" type="checkbox"/>
	If the report is submitted after its due date, the grantee provided an adequate justification for the delay. <input type="checkbox"/>
<b>Project Progress</b>	This section does not contain single-line responses (e.g., milestone delayed, milestone in progress) i.e., adequate context or explanatory information is provided. <input checked="" type="checkbox"/>



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	<p><i>Milestones:</i> The milestones listed in the report, and corresponding dates match those previously agreed to (either in the agreement or variation, as last agreed to by both Health and the grantee).</p>	<input checked="" type="checkbox"/>
	<p>There are adequate comments provided against each milestone/objective.</p>	<input checked="" type="checkbox"/>
	<p>There is sufficient information provided to enable Health to make an informed assessment regarding project progress.</p>	<input checked="" type="checkbox"/>
	<p><i>Risks:</i> Where a grantee has stated milestones are not on track, adequate detail on the reason for and extent of delays and a strategy to rectify have been provided.</p>	<input checked="" type="checkbox"/>
	<p><i>Variations:</i> Variation requests for new changes have been/ are in the process of being submitted. Variations previously approved have been included in the report.</p>	<input checked="" type="checkbox"/>
Project Expenditure	<p>The grantee has provided adequate financial information to date.</p>	<input checked="" type="checkbox"/>
	<p>The grantee has reported expenditure against the same categories as that in the grant agreement.</p>	<input checked="" type="checkbox"/>
	<p>Discrepancies between budgeted and actual expenditure are supported by adequate justifications in the comment column.</p>	<input checked="" type="checkbox"/>
	<p>Where partner contributions are being made toward a grant, the grantee has reported the contributions received to date.</p>	<input checked="" type="checkbox"/>
Project Evaluation	<p>The Measures of Success question has been addressed, where applicable (<i>this section only applies where a Measures of Success statement was requested with the application per the associated grant opportunity guidelines</i>).</p>	<input type="checkbox"/>
	<p>This section does not contain single-line responses (e.g., progressing as planned) i.e., adequate explanatory information is provided.</p>	<input type="checkbox"/>
	<p>Information included for public release is free from jargon.</p>	<input type="checkbox"/>
	<p>Evidence to demonstrate successful completion of the project is provided (<i>for Final Reports only</i>).</p>	<input type="checkbox"/>
	<p>Copies of any published reports and promotional material is provided (<i>for Final Reports only</i>).</p>	<input type="checkbox"/>
Attachments	<p>All relevant attachments provided by the grantee and outlined in the above attachments table are included with this report for Health's consideration.</p>	<input checked="" type="checkbox"/>



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**Comments** – The grantee confirms that despite some delays, the project is nearly completed and proceeding well to meet the grant requirements by the agreed end date and expend all grant funds in accordance with the agreement.

Actioning officer at BGH	S 22		06/02/2023
Reviewing officer at BGH	S 22		07/02/2023

HMRO

<b>Report Finalisation</b> <i>for completion by HMRO and to be provided to BGH post report assessment</i>		
Delegate decision on progress report	Select	[dd/mm/yyyy]
Delegate decision on associated payment (where applicable)		Select
HMRO risk rating <i>(for internal use only)</i>		Select
Comments: [Summarise any action items for BGH]		

## Attachment C - Certification of certain matters by the auditor

The department also requires a certification of certain matters by the auditor in addition to the independent audit report. This should be submitted with the statement of grant income and expenditure and independent audit report.

The auditor who signs this certification must also initial and date a copy of the Grantee's statement of eligible expenditure. The department will not accept an independent audit report that lacks this attachment.

The required format of certification is on the following page.



Department of Industry, Science and Resources  
GPO Box 2013  
Canberra ACT 2601

I understand that the Commonwealth, represented by the Department of Health and Aged Care, and National Stroke Foundation have entered into a grant agreement for the provision of financial assistance under the Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation) to the Grantee for the project. A condition of funding under the grant agreement is that the Grantee provides a statement of grant income and expenditure certifying that expenditure on approved project items has been incurred within the relevant audit period and paid in accordance with the grant opportunity guidelines, and is supportable by appropriate documentation.

In fulfilment of the condition, I hereby certify that:

- a. I am a member of Chartered Accountants Australia and New Zealand/ CPA Australia/ the Institute of Public Accountants (as a Public Practice Certified Member).
- b. I have prepared the independent audit report on National Stroke Foundation's, statement of grant income and expenditure in accordance with the details of the grant agreement between the Grantee and the Commonwealth, project no EPCD000019 dated 23/07/2018.
- c. I have reviewed the grant agreement between the Grantee and the Commonwealth, project no EPCD000019 dated 23/07/2018, and related grant opportunity guidelines and understand the requirements pertaining to financial reporting and eligible expenditure contained therein.
- d. I have signed the attached copy of National Stroke Foundation's statement of eligible expenditure that I used to prepare the independent audit report.
- e. I have complied with the professional independence requirements of Chartered Accountants Australia and New Zealand/ CPA Australia/the Institute of Public Accountants. I specifically certify that I:
  - i am not, and have not been, a director, office holder, or employee of National Stroke Foundation or related body corporate of National Stroke Foundation
  - ii have not been previously engaged by National Stroke Foundation for the purpose of preparing their Medical Research Future Fund – Accelerated Research – neurological (National Stroke Foundation) application or any report required under the grant agreement
  - iii have no financial interest in National Stroke Foundation.

S 22

Signature .....

Name

Qualifications Registered Company Auditor

Position Partner

Date 28/03/2024

release und t  
Archived: Friday, 13 March 2026 12:44:51 AM

From: [MRFF EP](#)

Mail received time: Mon, 17 Feb 2025 04:02:46

Sent: Mon, 17 Feb 2025 03:58:56

To: [Loucas, Maria Accelerated Research Program](#)

Cc: [MRFF EP](#) S 22

Subject: RE: Approved - End of Project Report/EPCD000019 [SEC=OFFICIAL]

Importance: Normal

Sensitivity: None

Attachments:

[EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - BGH Assessment.DOCX](#);

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\ri100OFFICIAL

**CAUTION** - This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Hi S 22

Thanks for following this up – S 22

Please see attached.

Thanks and kind regards

S 22

---

From: S 22

Sent: Wednesday, 12 February 2025 11:19 AM

To: MRFF EP ; Accelerated Research Program

Subject: FW: Approved - End of Project Report/EPCD000019 [SEC=OFFICIAL]

\qc\ri100\sb100\foffICIAL

\sb100

Hi S 22 and team,

S 22

May I please ask that you fill this in and return to us as soon as possible.

Kind Regards,

S 22

Business Grants Hub Division

Ngunawal Country , Industry House, 10 Binara Street, GPO Box 2013 Canberra ACT 2601 Australia

Department of Industry, Science and Resources

Phone S 22 | Email S 22 @industry.gov.au

\qcOFFICIAL

**From:** MRFF EP <MRFF.EP@health.gov.au>

**Sent:** Monday, 10 February 2025 1:17 PM

**To:** Accelerated Research Program <arp@industry.gov.au>

**Cc:** S 22 @industry.gov.au; S 22 @industry.gov.au; MRFF EP

<MRFF.EP@health.gov.au>

**Subject:** Approved - End of Project Report/EPCD000019 [SEC=OFFICIAL]

\qc\ri100\sb100\foOFFICIAL

\sb100

**CAUTION** - This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Hi S 22

Please be advised that the End of Project Report for EPCD000019 - National Stroke Foundation has been APPROVED by the delegate.

Please find the BGH assessment document attached.

Kind regards,

S 22

**From:** Accelerated Research Program <arp@industry.gov.au>

**Sent:** Thursday, 18 July 2024 10:15 AM

**To:** MRFF EP <MRFF.EP@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; MRFF

<MRFF@health.gov.au>; MRFF GMO <MRFF.GMO@Health.gov.au>

**Cc:** S 22 @industry.gov.au; S 22 @industry.gov.au

**Subject:** RE: End of Project Report/EPCD000019 [SEC=OFFICIAL]

\qc\ri100\sb100\foOFFICIAL

\sb100

Good Morning,

The Grantee has provided an updated version of their submitted End of Project Report which was originally submitted for your

consideration on April 24, 2024.

The Grantee wishes to advise of the updated activities, which have been highlighted in an updated copy of the report (see attached).

Importantly, the update addressed the response provided at Question 11 regarding the findings of the PESTO trial (page 11 in the updated report). As noted in the same response, a journal publication is being prepared for submission by 30 July 2024.

The Grantee has advised of the outcome of its consideration for publication in due course.

If you require any further information, please let me know.

Kind regards,

S 22

**Grants Manager**

Business Grants Hub & Integrity Division | External Programs Branch

Department of Industry, Science and Resources

Phone S 22 | Email S 22 @industry.gov.au

\qcOFFICIAL

**From:** S 22 @industry.gov.au>

**Sent:** Wednesday, April 24, 2024 4:40 PM

**To:** MRFF EP <MRFF.EP@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; MRFF@health.gov.au

**Cc:** S 22 @industry.gov.au>; S 22 @industry.gov.au>

**Subject:** End of Project Report/EPCD000019 [SEC=OFFICIAL]

\qc\ri100\sb100\foffICIAL

\sb100

Good Afternoon,

Please find attached the End of Project Report, it's attachments and the BGH Assessment of the Report.

If you have any questions, please let me know.

Kind regards,

S 22

**Grants Manager**

Business Grants Hub & Integrity Division | External Programs Branch

Department of Industry, Science and Resources

\qcOFFICIAL

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

\f0

\f0"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."



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Department of Health and Aged Care

Medical Research  
Future Fund



## Medical Research Future Fund Progress and Final Report Checklist

<b>Grant ID</b>	EPCD000019
<b>Lead Chief Investigator</b>	<ul style="list-style-type: none"> <li>▪ S 22 (National Stroke Foundation)</li> <li>▪ S 22 (Return to life PESTO)</li> <li>▪ S 22 (Return to work)</li> </ul>
<b>Institution/Organisation</b>	National Stroke Foundation
<b>Grant Title</b>	Emerging Priorities and Consumer Driven Research Initiative
<b>Grant Opportunity</b>	Medical Research Future Fund – Accelerated Research – Neurological (National Stroke Foundation)
<b>Report Due Date</b>	31/03/2024
<b>Report Period</b>	23/07/2018 to 31/12/2023
<b>Date Report Provided to BGH</b>	28/03/2024
<b>ANZCTR Trial ID</b>	<ul style="list-style-type: none"> <li>▪ Return to life' - Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976</li> <li>▪ S 22</li> </ul>
<b>Total Value of Grant</b>	\$2,500,000
<b>Value of Payments to date</b>	\$2,500,000
<b>Report Linked to a Payment?</b>	No
<b>Next Payment Due Date</b>	N/A
<b>Next Payment Amount</b>	N/A
<b>Previous Risk Rating</b>	Low

The following information has been supplied by the grantee and is being provided to the Department of Health and Aged Care to inform its review of grant progress and/or completion:

Attachment Name	Description
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - Grantee Submission.pdf	End of Project Report – Submitted by Grantee
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - WORK Trial Poster.pdf	Poster providing information and statistics on Vocational Rehabilitation Interventions Provided After Stroke
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - Independent Audit Report.pdf	Independent Audit Report by Pitcher Partners
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - Independent Audit Report 2.pdf	Independent Audit Report with expenditure using template.
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - Certification of Audit Report.pdf	Certification of Audit Report
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - PESTO Study Protocol Manuscript	A Empirical Research paper of the PESTO program
EPCD000019 - NATIONAL STROKE FOUNDATION - Final Report - PESTO Abstract Submission.pdf	A summarisation of the PESTO program



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Department of Health and Aged Care

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Future Fund



In alignment with the reporting requirements for MRFF grants, I can confirm that the report provided has been quality checked against the following: *(tick each box to confirm completion; If unable to tick, note in comments where not applicable or where followed-up with Grantee, and also provide further requested information to Health)*

Project Information	Project information such as Grant ID, title, institutional/ organisational details are correctly filled out.	<input checked="" type="checkbox"/>
	If the report is submitted after its due date, the grantee provided an adequate justification for the delay.	<input checked="" type="checkbox"/>
Project Progress	This section does not contain single-line responses (e.g., milestone delayed, milestone in progress) i.e., adequate context or explanatory information is provided.	<input checked="" type="checkbox"/>
	<i>Milestones:</i> The milestones listed in the report, and corresponding dates match those previously agreed to (either in the agreement or variation, as last agreed to by both Health and the grantee).	<input checked="" type="checkbox"/>
	There are adequate comments provided against each milestone/objective.	<input checked="" type="checkbox"/>
	There is sufficient information provided to enable Health to make an informed assessment regarding project progress.	<input checked="" type="checkbox"/>
	<i>Risks:</i> Where a grantee has stated milestones are not on track, adequate detail on the reason for and extent of delays and a strategy to rectify have been provided.	<input type="checkbox"/>
	<i>Variations:</i> Variation requests for new changes have been/ are in the process of being submitted. Variations previously approved have been included in the report.	<input type="checkbox"/>
Project Expenditure	The grantee has provided adequate financial information to date.	<input checked="" type="checkbox"/>
	The grantee has reported expenditure against the same categories as that in the grant agreement.	<input checked="" type="checkbox"/>
	Discrepancies between budgeted and actual expenditure are supported by adequate justifications in the comment column.	<input checked="" type="checkbox"/>
	Where partner contributions are being made toward a grant, the grantee has reported the contributions received to date.	<input checked="" type="checkbox"/>
Project Evaluation	The Measures of Success question has been addressed, where applicable <i>(this section only applies where a Measures of Success statement was requested with the application per the associated grant opportunity guidelines)</i> .	<input type="checkbox"/>
	This section does not contain single-line responses (e.g., progressing as planned) i.e., adequate explanatory information is provided.	<input checked="" type="checkbox"/>
	Information included for public release is free from jargon.	<input checked="" type="checkbox"/>



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Evidence to demonstrate successful completion of the project is provided *(for Final Reports only)*.

Copies of any published reports and promotional material is provided *(for Final Reports only)*.

#### Attachments

All relevant attachments provided by the grantee and outlined in the above attachments table are included with this report for Health's consideration.

#### Comments

S 22

#### 2. PESTO Trial:

This phase 2b trial is one of the first randomised studies to focus on pharmacological treatment for stroke recovery in young adults. It examines inflammatory pathways in stroke recovery, aiming to offer new treatments for those affected by stroke. If successful, the trial could provide a cost-effective treatment option using etanercept.

S 22

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The project has been delivered in line with the Grant Agreement. The grantee has advised that all Milestones have been completed successfully except for the study protocol and publication milestones (10 & 12) for the PESTO project. The grantee has stated that the Study Protocol manuscript has been submitted for peer review and an abstract has been submitted for the European Stroke Organisation Conference in May 2024 and they are aiming for publication of the final results in July 2024. The final results will be made available to the MRFF office.

S 47G



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- The Final Report financials has been audited and signed off by an independent auditor.

Please note that the project had 3 Chief Investigators, one for each section of the project.

Overall, these initiatives demonstrate ongoing progress in stroke care, with an emphasis on utilising current research to improve outcomes for patients and support young stroke survivors' return to work and daily life. The grantee has fulfilled the requirements of the grant as outlined in the grant agreement.

Actioning officer at BGH	S 22		24/04/2024
Reviewing officer at BGH	S 22		24/04/2024

HMRO

<b>Report Finalisation</b> <i>for completion by HMRO and to be provided to BGH post report assessment</i>		
Delegate decision on progress report	Approved	10/02/2025
Delegate decision on associated payment (where applicable)		Not applicable
HMRO risk rating <i>(for internal use only)</i>		Low
Comments: N/A		



EPCD - NATIONAL STROKE FOUNDATION - Saved Application

NATIONAL STROKE FOUNDATION Applicant Details EPCD000019 Application ID Closed Status Reason \$2,500,000 Agreed Grant Amount

Application Overview Risk Rating Related Applications and Parties Application Key Details Contacts Assessments Budget and Decision Milestones Conditions Raise Purchase Order Notify Applicant Reports and Payments

Report ID	Report Title	Report Type	Status Reason	Payment ID (Related Payment)	Period Start Date	Period End Date	Due Date
<input type="checkbox"/> EPCD0000191	EPCD Progress Report 1	Progress	Reviewed	EPCD0000192	30/07/2018	31/12/2018	30/01/2019
<input type="checkbox"/> EPCD0000192	EPCD Progress Report 2	Progress	Reviewed	EPCD0000193	1/01/2019	31/12/2019	30/01/2020
<input type="checkbox"/> EPCD0000193	EPCD Progress Report 3	Progress	Reviewed	EPCD0000194	1/01/2020	31/12/2020	30/01/2021
<input type="checkbox"/> EPCD0000196	EPCD Progress Report 4	Ad hoc	Reviewed		1/01/2021	31/12/2021	31/01/2022
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Payments

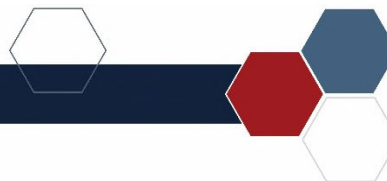
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<input type="checkbox"/> EPCD0000193	ARG7305500080751	Paid	29/02/2020	
<input type="checkbox"/> EPCD0000194	ARG7305500080754	Paid	28/02/2021	



Australian Government  
Department of Industry, Science and Resources

Medical Research  
**Future Fund**



S 22

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Dear S 22

**Medical Research Future Fund (MRFF) Emerging Priorities and Consumer Driven (EPCD) Research Initiative, Guidelines for Stroke Management and Return to life, return to work - recovery for young survivors  
Closure of File**

National Stroke Foundation : Project Number EPCD000019

I am writing to thank National Stroke Foundation for completing their Medical Research Future Fund (MRFF) Emerging Priorities and Consumer Driven (EPCD) Research Initiative Grant project. The Department of Health and Aged Care have now received all required reports in respect of project EPCD000019 and have determined that they are satisfactory. Therefore, all reporting obligations for the project have now concluded.

I would like to take this opportunity to thank you for your participation in the MRFF Emerging Priorities and Consumer Driven (EPCD) Research Initiative and wish National Stroke Foundation continuing success in your future health and medical research endeavours.

If you have any questions about the contents of this letter please contact me on S 22

Yours sincerely

S 22

Program Delivery  
External Programs Branch  
Business Grants Hub & Integrity Division  
Department of Industry, Science and Resources



## Grant Opportunity Guidelines

# Medical Research Future Fund Accelerated Research - neurological (National Stroke Foundation Inc)

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**Commonwealth policy entity:** Department of Health

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**Enquiries:** [arp@industry.gov.au](mailto:arp@industry.gov.au)

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**Date guidelines released:** 22 May 2018

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**Type of grant opportunity:** One off ad-hoc grant

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# 1. Grant opportunity overview and objectives

This grant opportunity is an element of the Accelerated Research program which forms part of the Medical Research Future Fund (the Fund).

## 1.1 About the Medical Research Future Fund

As part of the 2014-15 Budget, the Australian Government announced the establishment of the \$20 billion Fund to provide a sustainable source of funding for vital medical research over the medium to longer term. Through the Fund, the Government will deliver a major additional injection of funds into the health and medical research sector.

The objective of the Fund is to strategically fund research and address national priorities in a cohesive and coordinated way.

The Fund complements existing health and medical research and innovation funding to improve health outcomes through new grant opportunities. Grant funding targets identified national priorities determined by the independent Australian Medical Research Advisory Board consistent with the *Medical Research Future Fund Act 2015*. Grant opportunities will cover the entire research pipeline from basic to applied research with a focus on translation and commercialisation of discoveries. The Medical Research Future Fund Funding Principles underpin the Fund and ensure it continues to support investments that are priority driven, strategic, collaborative, and contestable with a focus on maintaining research integrity.

The intended outcomes of the Fund are:

- life changing discoveries such as new treatments, drugs and devices
- continuous improvement and innovation in the health system that benefits all Australians
- strengthening domestic research capacity through support, collaboration and the development of expert talent
- positioning Australia's health and medical research sector at the forefront of the innovation economy
- improving Australia's reputation as a global leader in health and medical research.

## 1.2 About the Accelerated Research program

The Accelerated Research program (the program) forms part of the Fund.

The objectives of the program are:

- to support research in emerging health priority areas and areas of unmet need, such as rare cancers, and rare diseases and illnesses

The intended outcomes of this program are:

- to provide new diagnoses, treatments and cures to those suffering from rare and debilitating conditions.

## 1.3 About the Neurological research grant opportunity

The objectives of this grant opportunity are to support neurological research.

The grant opportunity contributes to the achievement of the Department of Health's Outcome 1: Australia's health system is better equipped to meet current and future health needs by applying research, evaluation, innovation, and use of data to develop and implement integrated, evidence-based health policies, and through support for sustainable funding for health infrastructure.

The expected outcomes of the grant activity are to support a set of living guidelines that will revolutionise the translation of research into clinical practice. The Department of Industry, Innovation and Science (the department/we) will administer the grant in accordance with the [Commonwealth Grants Rules and Guidelines \(CGRGs\)](#)<sup>1</sup>.

## 2. Grant selection process

This grant opportunity has been established as a one-off or ad hoc grant.

The \$2.5 million grant over four years from 2017-18 to 2020-21 is to support a set of living guidelines that will revolutionise the translation of research into clinical practice. The grant will be up to 100 per cent of eligible project expenditure.

The grant is subject to an acceptable proposal from the National Stroke Foundation Inc which aligns with the goals and objectives of the Fund.

The Department of Health considers that this is an appropriate type of selection process as:

- there are a limited number of service providers capable of delivering the project
- the service provider has a well-established record of delivering the same or similar activities
- the nature of the granting activity is specifically dependent on the expertise of the National Stroke Foundation Inc.

## 3. Eligibility

To be eligible to receive a grant you must:

- be a legal entity, able to enter into a legally binding agreement
- have an Australian Business Number
- be invited to apply.

If you do not satisfy the eligibility criteria, you will not be considered.

### 3.1 Eligible grant activities

Eligible activities must directly relate to the project and can include:

- clinical trials, including a clinical trial with the Griffith University
- related research activities.

We may also approve other activities.

### 3.2 Eligible expenditure

You can only spend grant funds on eligible expenditure you have incurred on an agreed project as defined in your grant agreement.

Not all expenditure on your project may be eligible for grant funding. The program delegate makes the final decision on what is eligible expenditure and may give additional guidance on eligible expenditure if required.

To be eligible, expenditure must be:

- incurred by you within the project period

<sup>1</sup> <https://www.finance.gov.au/sites/default/files/commonwealth-grants-rules-and-guidelines.pdf>

- a direct cost of the project
- incurred by you to undertake required project audit activities.

Eligible expenditure items can include:

- direct labour costs of employees you directly employ on the core elements of the project. We consider a person an employee when you pay them a regular salary or wage, out of which you make regular tax instalment deductions
- contract expenditure is the cost of any agreed project activities that you contract to others
- domestic travel limited to the reasonable cost of accommodation and transportation required to conduct agreed project activities in Australia
- staff training that directly supports the achievement of project outcomes
- the cost of an independent audit of project expenditure up to a maximum of 1 per cent of total eligible project expenditure
- other eligible expenditure as approved by the program delegate.

If your proposal is successful, we will ask you to verify the project budget that you provided in your proposal when we negotiate your grant agreement. You may need to provide evidence such as quotes for major costs.

The grant agreement will include details of the evidence you may need to provide when you achieve certain milestones in your project. This may include evidence related to eligible expenditure.

If requested, you will need to provide the agreed evidence along with your progress reports.

You must keep payment records of all eligible expenditure, and be able to explain how the costs relate to the agreed project activities. At any time, we may ask you to provide records of the expenditure you have paid. If you do not provide these records when requested, the expense may not qualify as eligible expenditure.

At the end of the project, you will be required to provide an independent audit report of all eligible expenditure from the project.

You must incur the project expenditure between the project start and end date for it to be eligible unless stated otherwise.

### 3.3 Ineligible expenditure

Examples of ineligible expenditure include:

- expenses associated with business as usual activities not related to the delivery of the project
- financing costs, including debt financing and interest
- costs involved in the purchase or upgrade/hire of software (including user licences) and ICT hardware (unless it directly relates to the project)
- non-project-related staff training and development costs
- costs related to obtaining resources used on the project, including interest on loans, job advertising and recruiting, and contract negotiations
- costs related to preparing the grant proposal, preparing any project reports (except costs of independent audit reports we require) and preparing any project variation requests

This list is not exhaustive and applies only to the expenditure of the grant funds. Other costs may be ineligible where we decide that they do not directly support the achievement of the planned outcomes for the project or that they are contrary to the objective of the program.

You must ensure you have adequate funds to meet the costs of any ineligible expenditure associated with the project.

## 4. Ethics and research practices

Where applicable, research projects funded by Accelerated Research must conform to the principles outlined in the following:

- [NHMRC/ARC/UA Australian Code for the Responsible Conduct of Research \(2007\)](#)
- [NHMRC/ARC/UA National Statement on Ethical Conduct in Human Research \(2007, updated 2014\)](#)

## 5. The assessment criteria

Your proposal must provide sufficient information for us to evaluate the following assessment criteria:

### 5.1 Criterion 1

#### **The extent to which your project targets research in emerging health priority areas and fills gaps in research effort**

You should demonstrate this by identifying:

- a. the focus and expected outcome of your project (e.g. clinical trial and/or related research activities)
- b. how your project will accelerate neurological research
- c. how your project will support the development of a set of living guidelines that will revolutionise the translation of research into clinical practice.

### 5.2 Criterion 2

#### **Your capacity, capability and resources to deliver the project**

You should demonstrate this by identifying:

- a. access to appropriately skilled and experienced personnel, including technical
- b. access to infrastructure, capital equipment and technology
- c. access to and/or the beneficial use of any intellectual property
- d. a project plan and budget, including project risks
- e. an appropriate timetable and budget for the development of the project
- f. your ability to fund your share of project costs not covered by the grant.

### 5.3 Attachments to the proposal

We require the following documents with your proposal:

- project plan
- project budget

## 6. Grant assessment and decision making

We will assess your proposal and may seek information from any other source, including from within the Commonwealth.

In assessing your proposal we will consider:

- that the project represents value for money
- that the project can be delivered on time and to budget (as identified in supporting documents)
- that the project has been appropriately costed (the level and detail of the costing should be commensurate with the value of the project)
- that the level of risk associated with the project and its implementation is manageable and acceptable and it is acknowledged that risk may stem from a number of sources, such as new technology, the scale and complexity of the project
- that required approvals are in place, applied for, or otherwise expected to be received in the necessary timeframe to complete the project.

## 7. Who will approve the grant

Following assessment, we will make recommendations to the program delegate, a Commonwealth official who has been authorised to make decisions. The program delegate will make the final decision to approve a grant.

The program delegate's decision is final in all matters, including:

- the approval of the grant
- the grant funding amount to be awarded
- any conditions attached to the grant.

The program delegate must not approve funding if they reasonably consider the program funding available across financial years will not accommodate the funding offer, or if the proposal does not represent value for money.

We cannot review decisions about the merits of your proposal.

## 8. Notification of proposal outcomes

If you are successful, you will receive a written offer, including any specific conditions attached to the grant.

### 8.1 The grant agreement

You must enter into a legally binding grant agreement with the Commonwealth. We will use the Commonwealth Standard Grant Agreement. Standard terms and conditions will apply and cannot be changed. We will use a schedule to outline the specific grant requirements. We will identify any additional conditions attached to the grant in the grant offer or during the grant agreement negotiations.

We must execute a grant agreement with you before we can make any payments. You must not start any project activities until a grant agreement is executed.

If you enter an agreement under this grant opportunity, you cannot receive other grants for this project from other Commonwealth, state or territory granting programs.

The Commonwealth may recover grant funds if there is a breach of the grant agreement.

You will have 30 days from the date of a written offer to execute a grant agreement with the Commonwealth ('execute' means both you and the Commonwealth have signed the agreement). During this time, we will work with you to finalise details. The offer may lapse if both parties do not sign the grant agreement within this time. Under certain circumstances, we may extend this period. We base the approval of your grant on the information you provide in your proposal. We will review any required changes to these details to ensure they do not impact the project as approved by the program delegate.

## 9. Announcement of grants

Your awarded grant will be listed on the [GrantConnect](#) website within 21 days of the date of effect as required by Section 5 of the *CGRGs*.

## 10. Grant acquittal and reporting

You will be required to submit reports in line with the grant agreement. We will provide sample templates for these reports as appendices in the grant agreement. We will remind you of your reporting obligations before a report is due. We will expect you to report on:

- progress against agreed project milestones
- project expenditure, including expenditure of grant funds

We will monitor the progress of your project by assessing reports you submit and may conduct site visits to confirm details of your reports if necessary. Occasionally we may need to re-examine claims, seek further information or request an independent audit of claims and payments.

### 10.1 Progress reports

Progress reports must:

- include details of your progress towards completion of agreed project activities
- include the agreed evidence as specified in the grant agreement
- show the total eligible expenditure incurred to date
- include evidence of expenditure
- be submitted by the report due date (you can submit reports ahead of time if you have completed relevant project activities)
- be in the format provided in the grant agreement.

We will only make grant payments when we receive satisfactory progress reports.

You must discuss any project or milestone reporting delays with us as soon as you become aware of them.

### 10.2 End of project report

When you complete the project, you must submit an end of project report.

End of project reports must:

- include the agreed evidence as specified in the grant agreement
- identify the total eligible expenditure incurred for the project
- include evidence of expenditure
- be submitted by the report due date.

- be in the format provided in the grant agreement.

### 10.3 Ad-hoc report

We may ask you for ad-hoc reports on your project. This may be to provide an update on progress, or any significant delays or difficulties in completing the project.

### 10.4 Independent audit report

At the end of the project you must provide an independent audit report. An audit report will verify that you spent the grant in accordance with the grant agreement. The audit report requires you to prepare a statement of grant income and expenditure. The report template is attached to the grant agreement.

## 11. Grant evaluation

We will evaluate the grant to measure how well the outcomes and objectives have been achieved. Your grant agreement requires you to provide information to help with this evaluation.



# Return to life, return to work

Stroke Medical Research  
Future Fund Package

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# Return to life, return to work

## Stroke Medical Research Future Fund Package

### A targeted clinical research investment in stroke recovery for young survivors

- › **In partnership with the Australian Government via the Medical Research Future Fund (MRFF) the Stroke Foundation proposes to facilitate clinical research activity and promote greater access to innovative and cutting edge recovery treatments for stroke survivors of working age.**
- › Currently, an estimated 142,500 (30 percent of 475,000)<sup>1</sup> Australian stroke survivors are of working age. International evidence shows incidence of stroke among young people is increasing<sup>2</sup>.
- › Advancements in acute stroke treatment mean more Australians are surviving than ever before, but for the stroke survivor and their family the impact of the stroke is far reaching.
- › Young stroke survivors have unique unmet needs and require tailored services and supports to optimise their physical and psychological recovery and life post stroke.
- › There is a gap in high quality evidence regarding the effectiveness of recovery and rehabilitation interventions following stroke in adults of working age.
- › Australian researchers are leading the way in innovative thinking to enable younger stroke survivors to recover well, reducing the burden on individuals, their families, the community and the health system, and increasing productivity as more young survivors could return to work.
- › Young stroke survivors need and deserve to be able to actively engage with the community and optimally, to return to work.
- › The 'Return to life, return to work' research package will create better health outcomes for Australians, while driving investment and strengthening our economy.

<sup>1</sup> Deloitte Access Economics – Impact of stroke across Australia. 2014

<sup>2</sup> Feigin VL, Forouzanfar MH, Krishnamurthi R, Mensah GA, Connor M, Bennett DA, Moran AE, Sacco RL, Anderson L, Truelsen T, O'Donnell M, Venketasubramanian N, Barker-Collo S, Lawes CM, Wang W, Shinohara Y, Witt E, Ezzati M, Naghavi M, Murray C; Global Burden of Diseases, Injuries, and Risk Factors Study 2010 (GBD 2010) and the GBD Stroke Experts Group. Global and regional burden of stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. Lancet. 2014 Jan 18;383(9913):245-54.

## The human face of stroke

### Stephen Ward, 52

Stephen Ward is a very well regarded member and councillor in the Muswellbrook community.

Stephen suffered a stroke when he was 48.

Stephen has been left with physical, communication and some cognitive deficits (fatigue and memory). He is in a wheelchair, however can walk with a cane for small distances.

Prior to the stroke Stephen was an engineer. Today, Stephen is learning to read and write again by sharing books with son Patrick, aged 5. Stephen is married to Tracy and the couple's daughter Emily is 11.



### Paul Fink, 37

Melbourne man Paul Fink suffered a stroke three years ago at the age of just 34, not long after becoming a first time father. Paul spent six months in rehab, learning how to walk and talk again. Paul says he missed out on six months of his son Oscar's life as a result.

*"Prior to my stroke, I was very social, family-oriented and energetic. I was striving to be the best dad possible. My hobbies included reading, writing, travelling, photography, camping, sauna, community involvement and (of course) sports. I worked in accounting and IT in many roles, - usually small/medium companies with a focus on sports.*



*My stroke affected my speech and writing. I also have right dominant side paralysis (legs and arms). I am alive because of modern medicine and thanks to technology, I can write. This is possible because of speech therapy and a small device - my microphone (similar to Siri)."*

Through a lot of hard work and determination, Paul is learning to walk, to run, to speak and to write alongside Oscar, aged 4. Paul volunteers regularly at the Stroke Foundation in Melbourne with the aim of one day being able to return to work.

Stroke has devastated the life Paul and Lauren had planned, but the family celebrate every day and the opportunity it brings. This includes the upcoming birth of their second child.

## Desired outcomes

- › Life changing discoveries such as new treatments, drugs and devices.
- › Continuous improvement and innovation in the health system benefiting Australians.
- › Support research in the emerging health priority area of stroke.
- › Enhanced neurological research to ensure Australia's health system is better equipped to meet current and future health needs.
- › Strengthening domestic research capacity through support, collaboration and the development of expert talent.
- › Positioning Australia's health and medical research sector at the forefront of innovation.
- › Improving Australia's reputation as a global leader in health and medical research.

## Rationale

There are currently approximately 142,500 (30 percent of 475,000)<sup>1</sup> Australian stroke survivors who are of working age (between 18 and 64 years).

While there is a lack of solid local trend evidence in Australia, increasing rates of young or working age stroke have been observed internationally. Specifically, the Global Burden of Disease Stroke Experts Group noted a 25 percent increase in stroke incidence in people aged 20–64 years between 1990 and 2010.<sup>2</sup> The increasing rates of stroke in younger people worldwide are thought to be due, at least in part, to an increase in modifiable risk factors such as hypertension, diabetes and obesity.

Importantly, health and social care services are not well set up to deal with younger stroke survivors, and compared with those aged over 65 years, younger stroke survivors are less likely to be referred to rehabilitation services. As a consequence, many are returning home without the necessary follow-up therapy and support needed to resume everyday life, including returning to work. A 2013 systematic review of rehabilitation in younger stroke survivors identified a number of reasons why individuals had not resumed a regular work schedule, including fatigue, cognitive and memory problems, and anxiety.<sup>3</sup> This comes at a significant cost, not only to the individual, but to their family, health and social care services, and the economy as a whole.

A Deloitte Access Economics study commissioned by the Stroke Foundation estimated that in 2012, the cost of lost earnings caused by reduced employment due to stroke in people of working age in Australia was \$975 million.<sup>4</sup> In addition, the cost of absenteeism and lost home production due to stroke was estimated to be \$1.14 billion, while the cost of presenteeism (lower productivity while at work) was estimated to be \$0.7 billion.<sup>4</sup>

A key difference in the rehabilitation of younger stroke survivors is, on average, they will have to live longer with any residual disability. Without access to appropriate rehabilitation, living with this disability for a long period of time may result in significant dependency costs. For example, a study which examined the economic benefits of stroke rehabilitation for working aged adults reported it would take 21 weeks of inpatient rehabilitation in order for the rehabilitation to offset the cost of dependency.<sup>5</sup>

1. Deloitte Access Economics – Impact of stroke across Australia. 2014
2. Feigin VL, Forouzanfar MH, Krishnamurthi R, Mensah GA, Connor M, Bennett DA, Moran AE, Sacco RL, Anderson L, Truelsen T, O'Donnell M, Venketasubramanian N, Barker-Collo S, Lawes CM, Wang W, Shinohara Y, Witt E, Ezzati M, Naghavi M, Murray C; Global Burden of Diseases, Injuries, and Risk Factors Study 2010 (GBD 2010) and the GBD Stroke Experts Group. Global and regional burden of stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. *Lancet*. 2014 Jan 18; 383(9913):245-54.
3. Mahon H et al. Evidence-Based Review of Stroke Rehabilitation. *The Rehabilitation of Younger Stroke Patients*. 2013, p.4
4. Deloitte Access Economics – Impact of stroke across Australia. 2014

Yet most rehabilitation services are limited (median for all stroke is 28 days) and stroke survivors often describe the end of inpatient rehabilitation as stepping into the 'big black hole', where navigating ongoing recovery is up to them.

Unlike older stroke survivors, the evidence base for the effectiveness of stroke recovery and rehabilitation interventions for adults of working age is very limited.<sup>6</sup> In addition, there is a lack of high quality evidence on the effectiveness of vocational rehabilitation interventions in returning stroke survivors to work.<sup>7</sup> Importantly, there are a number of Australian researchers who are working on innovative projects in this area that will lead to significantly improved outcomes for patients in the near future. It is critical that this research is supported, in order to enable younger stroke survivors to recover well, thus reducing the burden on individuals, their families, the community and the health system, and increasing productivity and cost savings.

<sup>5</sup>. O'Connor RJ, Beden R, Pilling A, Chamberlain MA. What reductions in dependency costs result from treatment in an inpatient neurological rehabilitation unit for people with stroke? *Clin Med (Lond)*. 2011 Feb; 11(1):40-3.

<sup>6</sup>. <https://informme.org.au/en/Guidelines/Clinical-Guidelines-for-Stroke-Management-2017>

<sup>7</sup>. Hackett ML, Glozier N, Jan S, Lindley R. Psychosocial Outcomes in StrokE: the POISE observational stroke study protocol. *BMC Neurol*. 2009 Jun 12; 9:24.

## Stroke research in Australia

Stroke is a largely preventable and treatable disease. Research will help us beat it.

In 2016, funding for stroke research by the Australian Government through the National Health and Medical Research Council (NHMRC) equated to \$33.1 million, representing 4 percent of the total investment in medical research.<sup>8</sup>

The Stroke Foundation Research and Innovation Fund provides philanthropic grants to support Australian researchers in order to expand our collective knowledge and understanding about stroke, and has awarded nearly \$3 million in research grants to more than 190 researchers since 2008. The Research Grant Program, which is overseen by the Research Advisory Committee (RAC) of the Stroke Foundation Board (see Appendix A for RAC membership), is focused primarily on research that can translate into improving real world practice.

Australia is home to some of the leading minds in stroke.

Applications for the Stroke Foundation Research and Innovation Fund are highly competitive. Since 2009, applications to the Stroke Foundation Research and Innovation Fund have more than doubled. Demand for grants is increasing and there is significant opportunity for investment in worthwhile, robust projects.

There is now a significant opportunity to invest in the next stroke research breakthrough.

### Gaps in stroke research

There is a lack of high quality evidence regarding the effectiveness of recovery and rehabilitation interventions following stroke in adults of working age.

The evidence base for many stroke recovery and rehabilitation interventions lags behind the equivalent treatment pathways in acute stroke. This was evident in the recent update of the Clinical Guidelines for Stroke Management 2017. Many more people are now surviving stroke<sup>9</sup> thanks to breakthroughs in acute stroke treatment. For patients and families affected by stroke it is vital we gain a better understanding of the interventions which will enable stroke patients to make their best recovery possible.

To return to life and return to work after stroke.

<sup>8</sup>[www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data](http://www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data)

<sup>9</sup> AIHW Deaths in Australia, 7 February 2017 <https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia/contents/summary>

## The Proposal

The Federal Government, through the Medical Research Future Fund Accelerated Research - Neurological (MRFF), supports a **'Return to life, return to work' stroke research package**, to fund projects aimed at developing innovative recovery and rehabilitation clinical interventions for younger stroke survivors.

### The project

The MRFF 'Return to life, return to work' package will focus on clinical trials of recovery and rehabilitation interventions for stroke survivors. To be eligible for funding, proposals will need **to be ready to move into the clinical trial research phase**, with the potential for **rapid translation into real world practice**.

The proposed research package will be delivered through a **short (six week), open and transparent grant approval process** (outlined below), administered by the Stroke Foundation Research Advisory Council (RAC).

### Stage 1 Call for Expressions of Interest (EOI)

During this period, the 'Return to life, return to work' research package will be promoted to relevant stakeholders and organisations. Interested researchers will be invited to apply for clinical trial funding by completing a brief (two page) EOI form outlining their research proposal. The EOI form will request the following:

- › A brief overview of the applicant's qualifications, research experience and track record, including funding and publication highlights.
- › A brief research proposal, including project title, research focus, rationale (evidence gaps the research will address) and study methodology, including research objectives for years one, two and three of the project. Applicants will be asked to provide any pilot/feasibility data, if available.
- › A brief description of how the proposed research will translate into better patient outcomes, including clinical and health system impact. In addition, applicants will be asked what will be necessary for research findings to be translated into practice if the intervention is shown to be effective, taking into account engagement with consumers, health system/policy makers and how will this be achieved.

The RAC will contact potential grant reviewers during this period to determine their availability during the assessment period.

## **Stage 2 Assessment of research proposals**

Following the closing date, applications will be reviewed, and a summary of all projects will be sent to grant reviewers. Reviewers will be asked to notify the RAC of any conflicts of interest, and following this, research applications will be allocated to specific reviewers.

Once all reviewer scores have been received, applications will be ranked based on their score, and depending on the number of applications received, between three and five proposals will be short-listed for further consideration.

## **Stage 3 Selection of successful applicants**

Endorsement of each clinical trial will be sought from the Australasian Stroke Trials Network (ASTN), which will meet at the end of the assessment period to select two to three projects for funding. Successful applications will be presented to the Stroke Foundation Board for an expedited approval, before all successful and unsuccessful applicants are notified of the outcome.

## **Stage 4 Announcement**

The Australian Government will have the opportunity to announce individual grant recipients at its discretion in partnership with Stroke Foundation and the successful researcher institutions.

This process has been designed to reflect the Australian Government's high standards of probity and accountability, as well as reflect the vision and strategy of the MRFF. It is a transparent, equal process that ensures investment with the greatest potential to create better health outcomes for Australians.

As stated previously, proposals must be ready to move into the clinical trial research phase, with proven concepts or feasibility, with the potential for rapid translation into real world practice.

Asking researchers to identify multiple year goals assists by not only ensuring the potential for an immediate translation, it shows opportunities for continuous improvement, the development of a research pipeline and also commercialisation.

This project will result in healthier Australians and innovations that will boost national wealth. It will have a measurable impact on our health system's sustainability, productivity and health outcomes.

## Timeline and Milestones

The 'Return to life, return to work' research package presents the Department of Health and MRFF with a number of potential milestones.

Please note, this timeline provides a guide should grants be delivered over a three year process. Timelines can be shortened if grants were to be awarded over tightened time period.

	Year 1				Year 2				Year 3			
EOI	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Announcement of funding package.	■											
EOI	■											
Announcement of successful recipients	■											
<b>Commencement</b>												
Mid way report				■	■							
<b>Manage</b>												
Manage process, stakeholders and budget; report	■	■	■	■	■	■	■	■	■	■	■	■
<b>Evaluate</b>												
Conduct process evaluation				■	■							
Conduct outcome evaluation									■	■	■	
Publish results				■	■						■	■
Translate activities into practice (dependent on results)				■	■						■	■

Table 1: Timeline and milestones

In addition, ad hoc announcements may be made to publicise exciting results or research highlights published in peer-reviewed scientific literature, or presented at local, national and international conferences, or in the Australian and international media.

## Who we are

**The Stroke Foundation** is a national charity that partners with the community to prevent, treat and beat stroke. It is dedicated to empowering health professionals to deliver high quality best practice care to stroke patients. The Stroke Foundation advocates for better systems, processes and resources to help health professionals deliver world class stroke care. As the voice of stroke in Australia, the Stroke Foundation plays a vital role in supporting Australian researchers as they work towards the next innovation in stroke prevention, treatment and recovery.

The Stroke Foundation Research and Innovation Fund plays a vital role in supporting the next generation in stroke research. As the only national organisation working across all aspects of stroke in Australia, the Stroke Foundation has awarded nearly \$3 million in research grants to more than 190 researchers since 2008.

In 1983 the Stroke Foundation began as a research organisation and later became the Australian Stroke Neurosciences Institute with its dedicated research arm, the National Stroke Research Institute.

Research has been a cornerstone of the Stroke Foundation since its inception.

The Stroke Foundation's research program aims to support and translate high quality research into changes in practice, policy and knowledge to prevent stroke and improve quality of life for stroke survivors, their families and their caregivers.

## Research and Innovation fund highlights

- › [Pioneering clot retrieval/thrombectomy treatment](#) – Innovative research to improve treatment of ischemic stroke patients with large blocked vessels in the brain in whom standard clot-busting medication is less effective. Results changed the way stroke is treated nationally and internationally.
- › [Mobile Stroke Unit](#) – Australia's first 'stroke ambulance' with its on-board CT scanner is a ground breaking initiative that will enable faster diagnosis and treatment for people suspected of having a stroke. The Stroke Ambulance commenced operations in late November 2017.
- › [Technology-facilitated communication](#) to improve the door-to-treatment times for patients with acute stroke symptoms – Pulsara smart-phone app to determine if this technology can improve access to time-critical stroke treatment. The Pulsara app enables real-time, simultaneous communication between ambulance and hospital and emergency department staff.
- › [Stroke 123](#) – Evaluated the benefits of providing clinicians with integrated, high quality stroke data coupled with evidence-based clinical quality improvement program to help support better quality of stroke care in hospitals.

- › [Improving aphasia rehabilitation, giving survivors back their voice](#) – Trial to explore tele-rehabilitation. The trial utilised technology to deliver rehabilitation services to patients with aphasia in their own homes or local communities via the internet.

[More on the Stroke Foundation research program](#)

## Stroke Foundation Research Advisory Committee

### **Professor Amanda Thrift – Chair**

- › Professor Thrift is Head of the Epidemiology and Prevention Division, Stroke and Ageing Research, Monash University, and is an NHMRC Senior Research Fellow. She is a past President of the Stroke Society of Australasia and sits on numerous national and international advisory groups.
- › Professor Thrift gained her PhD from Monash University in 1995 in epidemiology in the study of risk factors for intracerebral haemorrhage. She has considerable research expertise in the epidemiology of stroke, having led the influential North East Melbourne Stroke Incidence Study (NEMESIS). This study has provided much of the evidence base for policy decisions around stroke in Australia.

### **Professor Julie Bernhardt**

- › Professor Julie Bernhardt is head of the Florey Institute of Neuroscience and Mental Health's stroke division and leads the AVERT Early Intervention Research Program – which has conducted the largest, international, acute stroke rehabilitation trial ever. Her multidisciplinary team of researchers is committed to the development and testing of new, rehabilitation interventions that aim to reduce the burden of stroke related disability.
- › Julie is Director of Australia's first NHMRC Centre of Research Excellence in Stroke Rehabilitation and Recovery, an exciting partnership to build capacity and research excellence in this exciting field, and led the first International Stroke Recovery and Rehabilitation Roundtable (SRRR) to establish new approaches to recovery research. The second roundtable is planned for 2018.

### **Professor Richard Lindley**

- › Professor Richard Lindley is a world-renowned geriatrician and stroke physician. He is co-Chair of Sydney Medical School's Lifespan Research Discipline who leads a portfolio of international clinical trials and projects that reliably assess new treatments in older individuals (with a particular interest in stroke management).
- › Richard's work has made significant contributions to medical science and health care policy nationally and internationally.
- › Professor Lindley has co-chaired the Australian Stroke Coalition, the Stroke Topic Working Group for the Australian Commission on Safety and Quality in Health Care and the development of national stroke guidelines (in Australia and Scotland). He is an Honorary Overseas Member of the Association of British Neurologists. He was Board Member of the Stroke Foundation and Chair of its Clinical Council for nine years (2006-2015).

**Ms Brenda Booth (consumer representative)**

- › Having had a stroke in 2001, Brenda is committed to supporting the development and advancement of stroke care so that stroke survivors and carers have better outcomes.
- › Brenda has been a consumer with the Agency for Clinical Innovation (ACI) Stroke Network Since 2004, a Consumer Council Member for the Stroke Foundation (2011-2016) and on the working party for Clinical Guidelines for Stroke Management (2007 & 2010), the Australian Commission on Safety and Quality in Health Care to develop a National Acute Stroke Clinical Care Standard (2013-14) and the Australasian College of Emergency Medicine review of thrombolysis 2015-2016.

**Professor Simon Koblar**

- › Professor Simon Koblar is a renowned stroke physician-scientist. He heads the Stroke Research Programme, which is a collaboration between the University of Adelaide (UA), The Queen Elizabeth Hospital (TQEH) and The Basil Hetzel Institute for Translational Medicine. Simon's major aims in Stroke research are: Repairing the Brain after a Stroke, The Molecular Pathology of Stroke, Genes and proteins involved in Stroke and Transient Ischaemic Attack (TIA).
- › Simon is patron for Stroke South Australia, was Chair of the South Australian Stroke Unit Network from 2006-9, a member of the Brain Foundation (SA) Ltd Board and in 2010, became an advisor to the Peter Couche Foundation, a body to support fund-raising for stroke research.

**Dr Caleb Ferguson**

- › Dr Caleb Ferguson, RN PhD, is an experienced educator and an early career nurse researcher. Since 2012, he has co-authored over 25 peer reviewed publications, 10 editorials and 4 book chapters. Caleb's main research interests are atrial fibrillation, chronic care, stroke and social media. In 2015, Caleb was awarded a Stroke Foundation Fostering Future Leaders Grant.

### **Dr Emma Power**

- › Dr Emma Power is a speech pathologist who has worked in the area of communication disorders following acquired brain injury for 20 years. She is a senior lecturer in the discipline of speech pathology at the University of Sydney. Her primary research interest is in evidence based practice (EBP) and the way we translate knowledge in to clinical policy and practice (implementation science). She also researches widely in the areas of aphasia and cognitive-communication disorders post traumatic brain injury.
- › Emma has developed and validated 82 Best Practice Statements for Post Stroke Aphasia Rehabilitation and developed an aphasia pathway website with implementation resources for clinicians ([www.aphasiapathway.com.au](http://www.aphasiapathway.com.au)).
- › Dr Power is a member of the NHMRC CCRE in Aphasia Rehabilitation. Dr Power has contributed to her professional and research community with previous roles as president of Speech Pathology Australia (NSW), committee member of SpeechBITE.

### **Dr Nadine Andrew**

- › Dr Nadine Andrew is a Senior Research Fellow with Peninsula Clinical School, Monash University and an NHMRC Early Career fellow. She has a clinical background in Physiotherapy, a Masters in Public Health and a PhD in epidemiology. Dr Andrew is currently leading a project in which data from the Australian Stroke Clinical Registry will be linked to Medicare and pharmaceutical data to provide insights into some of the services and care types being accessed by survivors of stroke living in the community, and how this contributes to patient outcomes.

### **Professor Ian Kneebone**

- › Professor Ian Kneebone completed undergraduate degrees at the University of Adelaide, a Masters degree in clinical psychology at the University of Western Australia and a doctorate in clinical psychology at the University of Surrey. He has specialised in rehabilitation and worked with older and younger people who have encountered stroke for over thirty years. He has published widely on stroke, including on the assessment and management of mood disorders, the coping of informal carers of people who develop speech and language problems and on breaking bad news.
- › Ian is currently a CI on a multi-centre NHMRC funded trial to investigate the prevention of depression in people with aphasia after stroke. Ian is a co-author of the seminal Psychological Management of Stroke, (Wiley, 2012) and was a member of the Core Steering Group that developed the National Stroke Strategy for England.

## Examples of ‘Return to life, return to work’ research projects

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Projects listed below are examples of possible studies that may be suitable for funding under the proposed 'Return to life, return to work' MRFF stroke package.

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## **The use of Perispinal Entanercept (PSE) or anti-TNF Treatment (tumor necrosis factor) as a therapy promoting recovery after chronic stroke**

The need: Chronic stroke remains a major unmet health problem in Australia and worldwide. Currently, no approved medical therapies have been shown to improve the long-term clinical deterioration caused by this condition when patients do not respond further to current rehabilitative therapies.

The Institute of Neurological Recovery (INR) in the US, promises to change current thinking about the potential for recovery of function, even years after the acute event. It treats patients with an off-label use of Perispinal Entanercept (PSE).

Entanercept (ENBREL) has been approved by the US Federal Drug Administration for many years as a therapy to treat inflammatory diseases such as rheumatoid arthritis. This drug has a well-characterised safety profile for these uses and is approved for such use in Australia. Researchers in the US have started investigating the usefulness of this drug in treating stroke.

The INR makes this new therapeutic approach available for selected patients. Individual results vary, not all patients respond. The INR also claims multiple treatments may be required.

According to the INR: “These unprecedented clinical results rely upon the Institute’s patented TransBarrier® drug delivery technology (multiple issued and pending U.S. and international patents, including U.S. patents 6419944, 6537549, 7214658, 7629311, 8119127, and 8236306, assigned to TACT IP, LLC and Australian patent 758,523), as published in the scientific literature and documented in independent news stories.”

le. The drug is injected into the patient’s spine and they are tipped upside down – thought to send the drug directly to the brain quickly and maximising its benefit. Please note there is currently no evidence that the drug can reach the brain.

Chronic stroke sufferers throughout Australia have been travelling to US clinics to obtain PSE therapy at great personal cost (around \$30,000).

The Solution: Stroke Foundation facilitates a robust, independent, multi-centred clinical trial of Perispinal Entanercept (PSE) or anti-TNF Treatment (tumor necrosis factor) as part of its Research and Innovation Program, in line with Australian Stroke Trials Network (ASTN) guidelines.

An independent, robust and multi-centred trial of Perispinal Entanercept (PSE) or anti-TNF Treatment (tumor necrosis factor) has the potential to change the way chronic stroke is treated in Australia and internationally. A successful trial will lead to improvements in stroke recovery, and importantly improved quality of life for stroke survivors and their families.

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## Conclusion

**The ‘Return to life, return to work’ research package will create better health outcomes for Australians, while driving investment and strengthening our economy.**

Today there are 142,500 (30 percent of 475,000) Australian stroke survivors of working age. International evidence shows incidence of stroke among young people is increasing.

Many more people are now surviving stroke thanks to breakthroughs in acute stroke treatment. Now, we must focus our attention on finding the next discovery in stroke rehabilitation. For patients and families affected by stroke it is vital we gain a better understanding of the interventions which will enable stroke patients to make their best recovery possible.

We know young stroke survivors and their families are doing it tough. Stroke happens in an instant impacting both mental and physical capabilities. In an instant, everything changes. Recovery from stroke can be long and challenging journey, but it can be improved.

Australian researchers are leading the way in innovative thinking to enable younger stroke survivors to recover well, but they need funding support to find the next innovation.

‘The Return to life, return to work’ research package will support our greatest minds to beat stroke. It will reduce stroke’s burden on individuals, their families, the community and the health system.

This process has been designed to reflect the Australian Government’s high standards of probity and accountability, as well as reflect the vision and strategy of the MRFF. It is a transparent, equal process that ensures investment with the greatest potential to create better health outcomes for Australians.

**This project will result in healthier Australians and innovations that will boost national wealth. It will have a measurable impact on our health systems sustainability, productivity and health outcomes.**

### Contact:

S 22

**National Manager Public Affairs and Advocacy  
Stroke Foundation**

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D +S 22

StrokeLine: 1800 STROKE (1800 787 653)

S 22

@strokefoundation.org.au



## Perispinal Etanercept to improve Stroke Outcomes (PESTO)

A prospective multicentre, phase 2b randomised controlled double-blind trial, to determine the safety and efficacy of perispinal etanercept on quality of life at 28 days post treatment ([PESTO Trial](#)).

### Updated Project Plan

This updated project plan is presented to the Department of Health and MRFF to support the project duration variation request for the PESTO trial.

	2022				2023				2024			
Study protocol	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Amendment submitted to HREC		■										
HREC approval			■									
Australia New Zealand Clinical Trials Registry Trial update			■									
Update trial information on online platforms			■									
Publication of study protocol and statistical analysis plan						■						
<b>Trial Governance</b>												
Data Safety and Monitoring Committee meetings		■			■			■				
Steering Committee meetings			■	■	■	■	■	■				
Stroke Foundation meetings			■	■	■	■	■	■				
<b>Recruitment</b>												
Promotion of the trial	■	■	■	■	■	■	■	■				
Develop patient interview and promote through social media and networks			■	■	■	■						
<b>Evaluate</b>												
Closure of sites								■				



	2022				2023				2024			
Conduct outcome evaluation									■	■		
Publication plan						■						
Final reporting									■			
Research translation activities (dependent on results)									■	■	■	■





## Schedule 2 Reporting requirements

### Appendix 1

Medical Research Future Fund: “Return to life, return to work.” A targeted clinical research investment in stroke recovery for young survivors.

#### Progress report requirements

Consistent with clause E (Reporting) of the Commonwealth grant agreement, the Grantee is required to provide the information requested below in its progress reports. The Commonwealth reserves the right to amend or adjust the requirements.

You must submit your report via the business.gov.au [portal](#) when it is complete.

#### Project Information

Grant ID: EPCD000019

Institution/Organisation: National Stroke Foundation

Grant Title: Emerging Priorities and Consumer Driven Research Initiative (July 2018)

Month and Year: July 2022 (Reporting period **01/01/2022 – 30/06/2022**)

Australia New Zealand Clinical Trials Registry Trial ID (where relevant):

Perispinal Etanercept to improve Stroke Outcomes (PESTO): ACTRN12620001011976

Early vocational intervention for people after stroke: A randomised pilot trial: ACTRN12619001164189

#### Project Progress

1. Complete the following table for each milestone or objective outlined in the Activity Schedule of your grant agreement or (if applicable) previous progress report, and any additional approved milestones.

The Comments field should summarise progress at the end of the reporting period towards completion of the agreed research activities relevant to each milestone/objective, and provide a justification for any changes or delays to milestones/objectives.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
1. Project start date	30/07/2018	30/07/2018	100%	
2. Call for research applications concludes	31/12/2018	30/11/2018	100%	
3. Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration	30/06/2019	28/06/2019	100%	<b>PESTO</b> - ASTN 28/06/2019; ethics 05/09/2019; governance 04/03/2020; trial registration-22/09/2020. <b>S 22</b>

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
4. Training of staff at trial sites concludes	31/12/2019	27/10/2020	100%	<b>PESTO</b> - Austin Health-27/10/2020, Canterbury Geriatric Medical (CGM) Research Trust (NZ) - 17/12/2020 & 14&18-01/2021. Alfred Health 09/04/2021. <b>S 22</b>
5. Publication of study protocol and statistical analysis plan	30/04/2022	<b>PESTO –</b> 30/06/2023 <b>S 22</b>	<b>PESTO -</b> 95% - Study protocol 70% - statistical analysis plan  <b>S 22</b>	Commentary addressing specific queries raised by the Department of Health is provided in Q3.
6. Patient recruitment concludes	30/04/2022	<b>PESTO -</b> 30/09/2023 <b>S 22</b>	<b>PESTO -</b> 52% <b>S 22</b>	<b>PESTO –</b> Current recruitment = 83 randomised participants/160 targeted (52%). Since January 2022 the team have recruited 23 patients (0.9 patients per week).  Commentary addressing specific queries raised by the Department of Health is provided in Q3.  <b>S 22</b>
7. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%	Data Safety and Monitoring Committee (DSMC) is established and performing for both trials, effectively completing this milestone. Data safety and monitoring extends until project completion. <b>PESTO -</b> DSMC next scheduled meeting is July 2022.

Milestone/Objective	Agreed End Date	Actual/Anticipated End Date	Current % Complete	Comments
8. Clinical Trial close out, closure of sites, results written up and presented, publication plan	31/12/2022	31/12/2023	45%	<b>PESTO</b> – Not started and pending variation request.  S 22
9. Project end date	31/12/2022	31/12/2023	45%	<i>Pending project duration variation request</i>

2. Describe progress towards completion of any additional research activities undertaken during the reporting period that are not captured in the table above.

3. Provide details of how you are managing, or propose to manage, risks to completion of milestones/objectives that have arisen during the reporting period.

**PESTO**

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The team have taken the following actions to maintain and increase recruitment at a steady level:

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Further plans include:

- using social media including a patient interview to raise awareness and the importance of the trial.
- hiring a clinical trial coordinator (within existing budget). The clinical trial coordinator will support contacting individual patients from participating hospital registries (Austin Health and Alfred Health) who fulfill entry criteria.

The team anticipate that an additional extension to December 2023 would allow 52 more weeks of recruitment. The team will need to recruit 1.2 patients (current rate 0.9 patients per week) to

recruit the remaining 77 patients (starting July 1). It is anticipated that the actions listed above will increase the current rate of 0.9 to the requisite 1.2 patients per week should the project duration variation be granted.

The study protocol is incorporating the last amendment to the protocol, as described above, prior to submission. The team anticipate this amendment will be approved by Austin Health ethics in August 2022. The team do not anticipate major delays in the publication. The optimal submission time was discussed with the trial statistician. The statistical analysis plan is on track to be finalised in September 2022, it is anticipated to take one month to complete.

If an extension is granted, existing participants will be informed of the extension so they are aware of the delay in reporting of project outcomes.

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4. Complete the following table for all variation requests approved, submitted (pending approval) or in draft (pending submission) for this grant to date.

Description of Variation	Current Status (Approved/Submitted/In Draft)
Project Duration Variation to extend to 31 December 2022	Approved.
Project Duration Variation to extend to 31 December 2023	Submission – 29 July 2022.

5. Provide a statement on your overall progress towards completion of the Research Activity by the agreed end date. If the Research Activity is not on track, describe the extent of the overall delay.

**PESTO**

Despite the recruitment challenges experienced to date, the trial has reached 52% of its recruitment target. This has been a well-regarded achievement among the research community. It is anticipated that the actions taken in Questions 3 will increase the recruitment rate from the current 0.9 to the requisite 1.2 patients per week should the project duration variation be granted.

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6. *Provide a summary of progress towards implementing your research findings and how you intend to ensure their translation to support improved health outcomes.*

You should include information about your proposed approach and any key enablers or barriers to implementation.

### **PESTO**

At this stage of the research, in the absence of conclusive findings, the team have not implemented this research. If the trial is conclusive, further evidence will be required to convince the stroke community and the TGA as this is a phase 2b trial, not a phase 3 trial. The results will be disseminated to participants and channels such as scientific paper(s), abstracts at conferences.

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7. *Complete the following table if your grant involves identifying, supporting and working in partnership with selected organisations to progress their own research project/s.*

**Question 7 applies to grants where the funded organisation is responsible for supporting research projects led by other organisations.**

Partner Organisation	Project Title	Summary of Project	Lead Researcher	Grant Funds Provided	Start Date of Project	% Project Complete
Not applicable						

## Project Expenditure

8. *Provide details of all expenditure incurred during the reporting period.*

Expenditure should be divided into the same categories as the budget in your grant agreement. The table should indicate budgeted and actual expenditure for the current reporting period. The Comments field should justify any differences between the budgeted and actual expenditure.

If you are registered for GST, enter the GST exclusive amount. If you are not registered for GST, enter the GST inclusive amount. We may ask you to provide evidence of costs incurred. Refer to the grant opportunity guidelines or contact us if you have any questions about expenditure.

Expenditure Item	Budget (AUD)	Actual (AUD)	Comments
Contract Expenditure	\$0	\$0	
Labour costs	\$0	\$0	
Travel costs	\$0	\$0	
Other eligible expenditure	\$ 47G	\$0	PESTO trial budget equates to the remaining other eligible expenditure of grant funds. \$ 22  Not reflecting any in-kind support provided by The Florey for PESTO, and National Stroke Foundation for \$ 22

9. Provide a statement confirming the eligibility of expenditure incurred during the reporting period. If grant funds have been used to cover costs for ineligible items, explain why.

The budget reallocation for PESTO has not impacted the overall project outcomes as sufficient funding is available to recruit the anticipated number of patients, execute project management, pay for statistical support and database maintenance. Approved budget reallocation and in-kind support of the administering institution provides for the delivery of the project activities over the extended project timeline at no additional financial cost.

The funds have been expended according to the grant opportunity guidelines. This has been ratified by the administering institution and Stroke Foundation.

10. Provide details of the estimated expenditure for the next reporting period.

Expenditure Item	Budget (AUD)
Contract Expenditure	\$0
Labour costs	\$0
Travel costs	\$0
Other eligible expenditure	\$ 47G

11. Provide details of any partner contributions received during the reporting period.

The Comments field should indicate whether each contribution has been made as expected. If not, describe the impact of any delays or changes on the delivery of the Research Activity.

Name of Partner	Type of Contribution	Value of Contribution	Comments
Not applicable			

## Project Evaluation

The [MRFF Monitoring, Evaluation and Learning Strategy](#) was published in November 2020.

**Question 12 must be completed if you provided a Measures of Success statement with your application, as specified in the grant opportunity guidelines. N/A**

12. Complete the following table for each outcome or result against which your contribution to the Measures of Success for the MRFF is being evaluated, as specified in the Measures of Success statement provided with your application.

For each Measure of Success, the table should:

- list each outcome/result (one per row), including a quantitative or qualitative description of the target that will indicate its achievement or completion
- summarise your anticipated and actual progress towards achievement or completion of the target at the end of the reporting period.

You may list several outcomes/results against a single Measure of Success.

Measure of Success	Outcome/Result	Anticipated Progress	Actual Progress

13. Provide a statement on the most important finding or outcome from your research during the reporting period, including any new or unexpected findings or outcomes.

Noting that your response may be used in public communications about the MRFF, please indicate whether any of the information you provide is commercial in confidence.

**PESTO**

The trial results are yet unknown, and no new unexpected findings or outcomes were observed. Recruitment through the Australian Stroke Clinical Registry has however led to local trial awareness and interest and provides an important avenue for future trial recruitment for stroke clinical trials.

S 22

14. Describe any enablers or barriers to the translation or implementation of your research that could be used to inform future MRFF funding opportunities.

**PESTO**

The biggest barrier to project completion has been the COVID-19 pandemic and recently, planning difficulties with flight cancellations.

For future opportunities, realistic timelines for clinical trials would be welcomed. Additionally, support for travel costs, advertising on social media and permission to expend funds overseas would increase future recruitment rates and speed up trial completion.

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## Certification

By submitting this progress report, you are certifying that:

- an authorised person has completed the report.
- the information in this report is accurate, complete and not misleading and that you understand the giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).
- you have complied with all funding conditions and relevant legislation applicable to the delivery of the Research Activity, as described in the grant agreement.

you are aware that the grant agreement empowers the Commonwealth to terminate the grant agreement and to request repayment of funds paid to the grantee where the grantee is in breach of the grant agreement.