ABN 92 124 762 027

THE FLOREY

Thursday, March 19th, 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
www.florey.edu.au

Media Release

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.

s22

Media Contact: s47F e: media@strokefoundation.org.au

Australian Government
Department of Health

To:
Dr Masha Somi
Chief Executive Officer
Health and Medical Research Office

BULK APPROVAL OF GRANT VARIATIONS
MEDICAL RESEARCH FUTURE FUND (MRFF) – EMERGING PRIORITIES AND CONSUMER DRIVEN RESEARCH INITIATIVE – UNLINKING OF FINAL PROJECT PAYMENTS FROM FINAL REPORTS FOR FOUR AD-HOC GRANTS

Purpose
As the Departmental delegate and approver, under sections 15A, 26 and 27 of the *Medical Research Future Fund Act 2015* (MRFF Act), that you:

APPROVE:

1. the proposed bulk Agreement of Variations at **Attachment A**, **B**, **C** and **D**, unlinking final payments from the provision of final reports, and providing an 18 month extension for s22 National Stroke Foundation, s22 to undertake research activities under their grant agreements for their respective projects.

NOTE:

2. that a bulk Agreement of Variation is the appropriate mechanism for the proposed variation as it has financial implications, prompts changes to the content of the original agreements and increases the grantee's obligations under the Grant Agreement, which are described in the **Background**
3. that the proposed variations include the revised dates for the Activity, the Agreement and submission of a number of reports as described in this document (see **Background**), and payment of the grant
4. that if you approve, the Business Grants Hub (BGH), which is administering the grants, will issue the Agreement of Variation to each grantee for signing, and once signed the Agreements will be returned to you for execution.

Approval Timing
Approval of the proposed Agreement of Variations is requested by 4 June 2021 to ensure payments are made before the end of the 2020-21 financial year.

Background
Prior to Budget 2019-20, the EPCDR Initiative was titled the 'Accelerated Research Program' and was almost exclusively made up of ad-hoc grant opportunities administered by BGH. In May 2020, you approved bulk variations (**Attachment E**) to unlink final payments from final progress reports. BGH has recently notified the Emerging Priorities and Researchers Section that they had identified four additional Accelerated Research projects (now EPCDR) which have payments due in 2020-21, and are

linked against deliverables (satisfactory completion of a final project report and independent audit report) that are due in later financial years. Details of these research projects can be found below in **Table 1**. BGH advise that linking the final payment to the receipt of a satisfactory final report and independent audit report was a former risk mitigation strategy implemented in 2018 by BGH as it was thought it would address any potential risks that may arise with the grant agreement. Since 2019 however, this risk mitigation strategy is no longer in place and does not align with current program management approaches used by HMRO.

In all four of the grantee's January 2021 Progress Report, it is has also been reported that Covid-19 has significantly impacted on their project milestones. These delays have been well articulated by each grantee, and generally relate to issues with recruitment or ability to undertake clinical research (see **Table 1** below). Specific information relating to delays is discussed in each grantees progress report. Progress report assessments by the Department are to be completed following the outcome of the proposed variations and will be available in TRIM.

Table 1

Grantee	Project title	Grant value	2020-21 payments remaining	Reason(s) for variation request	Revised Activity Completion Date
s22					
National Stroke Foundation	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	s47(1)(b)		• Grant agreement discrepancy between Part D and Part E • Enable payment of 2020-21 funding • Covid-19 related delays impacting: participant recruitment; ethics approval; staffing	31 December 2022 (original project end date 30 June 2021)
s22					

On 25 May 2021, the Department received a formal variation proposal for each grantee from BGH, who is administering the grants (**Attachment F**). As all four grantees January 2021 progress reports are currently under assessment, we recommend the following:

- unlinking the payment with the final report so that a payment can be made in 2020–21
- combining the progress report payment and final report payment
- extending the Activity Completion date by 18 months to enable grantees to complete their projects
- adjusting the Reporting Schedule to account for the extension.

Risk Assessment

If the funds are not paid in 2020-21, there is the risk of the funds being forfeited for 2020-21 and will impact the overall availability of funds in 2021-22 from the Emerging Priorities and Consumer Driven Research Initiative. By unlinking the final payment from the receipt of final reports, and linking it to each grantees current progress report, the Department is able to fulfil its obligations by making payments for all funding allocated in the 2020-21 financial year.

Next steps

If approved, BGH will issue an Agreement of Variation to each grantee. Once signed, they will be returned to you for execution.

Documentation

All relevant documentation pertaining to the proposed variation has been filed (in accordance with Corporate Business Rule 2: Records Management) in TRIM at D21-739550.

Recommendations

As the Departmental delegate and approver, under sections 15A, 26 and 27 of the Medical Research *Future Fund Act 2015* (MRFF Act), that you:

1. **APPROVE** the proposed bulk Agreement of Variations at **Attachment A**, **B**, **C** and **D**, unlinking final payments from the provision of final reports, and providing an 18 month extension for s22 , National Stroke Foundation, s22 to undertake research activities under their grant agreements for their respective projects.	**Approved ~~/ Not Approved~~**
2. **NOTE** that a bulk Agreement of Variation is the appropriate mechanism for the proposed variations as it has financial implications, prompts changes to the content of the original agreements and increases the grantee's obligations under the Grant Agreement, which are described in the **Background**	**Noted ~~/ Please Discuss~~**
3. **NOTE** that the proposed variations include revised dates for the Activity, the Agreement and submission of a number of reports as described in this document (see Background), and payment of the grant	**Noted ~~/ Please Discuss~~**
4. **NOTE** that if you approve, the Business Grants Hub (BGH), which is administering the grants, will issue the Agreement of Variation to each grantee for signing, and once signed the Agreements will be returned to you for execution	**Noted ~~/ Please Discuss~~**

[Authorised electronically]

Dr Masha Somi
Chief Executive Officer
Health and Medical Research Office
2 June 2021

Attachments:

A s22
B National Stroke Foundation Agreement of Variation
C
D s22
E
F

Contact officer: s22
Phone:
E/A Corro Ref: N/A
TRIM ref: D21-739550

Australian Government
Department of Industry, Science, Energy and Resources

FOR OFFICIAL USE ONLY

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. s22
2. **National Stroke Foundation (EPCD000019)**
3. s22
4.

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.

Issues:

s22

2. National Stroke Foundation (EPCD000019)

This agreement totalling s47(1)(b) was executed on 23 July 2018 and has a current project end date of 30 June 2021. There is s47(1)(b) remaining to be paid by 30 June 2021 scheduled across two payments:

- A Progress Report (s47(1)(b)) – this assessment is with Health for decision;
- A Final Report and Audit (s47(1)(b) – this final payment is due by 30 June 2021 although the final reports are due in September 2021. Without an amendment to the agreement this payment cannot be made.

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).

s22

s22

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 s22 from the team on (s22 .

Kind regards,

s22

Program Manager
Business Grants Hub

24 May 2021

ATTACHMENTS

A: s22
B: Draft Agreement of Variation – National Stroke Foundation (EPCD000019)
C: s22
D: s22

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	**Commonwealth**
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	**Grantee**
Address details	**Physical** National Stroke Foundation Level 7, 461 Bourke Street MELBOURNE VIC 3000 **Postal** 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.

Table of Contents

Agreed terms

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 1 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 s47(1)(b) .

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

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

Masha Somi

Digitally signed by Masha Somi
Date: 2021.06.07 17:56:22 +10'00'

Signature of delegate

Dr Masha Somi

Name of delegate (print)

Chief Executive Officer
Health and Medical Research Office

Position of delegate (print)

Date 7 June 2021

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

s47F

Signature of authorised representative
(Please delete as applicable)

s47F

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 - "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 s47(1)(b) (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
s47(1)(b)		

Payment event	Payment amount (GST exclusive)	Payment date
s47(1)(b)		
Total	s47(1)(b)	

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:

Eligible expenditure item	Estimated expenditure 2018-19	Estimated expenditure 2019-20	Estimated expenditure 2020-21	Estimated expenditure 2021-22	Estimated expenditure 2022-23	Total
Labour and contract	s47(1)(b)					
Travel costs						
Other eligible expenditure						
Total						

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

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						■						
Trial Governance												
Data Safety and Monitoring Committee meetings		■			■			■				
Steering Committee meetings			■	■	■	■	■	■				
Stroke Foundation meetings			■	■	■	■	■	■				
Recruitment												
Promotion of the trial	■	■	■	■	■	■	■	■				
Develop patient interview and promote through social media and networks			■	■	■	■						
Evaluate												
Closure of sites								■				

	2022				2023				2024			
Conduct outcome evaluation												
Publication plan												
Final reporting												
Research translation activities (dependent on results)												

Australian Government

Department of Health and Aged Care

To:
Dr Masha Somi
Chief Executive Officer
Health and Medical Research Office

APPROVAL OF GRANT VARIATION
MEDICAL RESEARCH FUTURE FUND (MRFF) – EMERGING PRIORITIES AND CONSUMER DRIVEN RESEARCH INITIATIVE
NATIONAL STROKE FOUNDATION – AUSTRALIAN LIVING GUIDELINES FOR STROKE MANAGEMENT AND "RETURN TO LIFE, RETURN TO WORK" - A TARGETED CLINICAL RESEARCH INVESTMENT IN STROKE RECOVERY

Purpose
As the Departmental delegate and approver, under sections 26 and 27 of the *Medical Research Future Fund Act 2015* (MRFF Act), that you:

APPROVE:

1. the proposed Variation Contract at Attachment A, providing a defer in progress request for the National Stroke Foundation to undertake research activities under the grant agreement for the 'Australian Living Guidelines for Stroke Management and "Return to life, Return to work" – A targeted clinical research investment in stroke recovery for young survivors' project providing a:
    a. 12-month extension to the Activity Completion Date from 31 December 2022 to 31 December 2023
    b. 12-month extension to the Agreement End Date from 30 June 2023 to 30 June 2024.

NOTE:

2. that a Variation Contract is the appropriate mechanism for the proposed variation as it prompts numerous changes to the content of the original agreement, which are described in the **Background**
3. that the Variation Contract applies to one variation type as per the MRFF Grant Variation Policy:
    a. a 'Defer an in-progress grant' variation as it makes changes to Activity and Agreement dates post Activity Commencement Date
4. that the proposed variation includes revised Activity Completion and Agreement End dates, Activity Schedules, milestones, reporting schedule, and Activity Budget
5. that an updated Risk Management Plan has been provided by the grantee which identifies key risks and mitigation strategies up to the proposed extended Activity Completion date (Attachment B)
6. that if you approve, the Business Grants Hub (BGH), which is administering the grant, will:
    a. issue the Variation Contract to the grantee for signing, and once signed it will be returned to you for execution

b. advise the grantee that if they require a further extension to the grant activity that they will be required to demonstrate exceptional circumstances in line with the MRFF Grant Variation Policy.

Approval Timing

Approval of the proposed Variation Contract is requested by 20 October 2022 to allow the grant to progress as per the variation.

Background

National Stroke Foundation was a successful applicant to the 2018 Accelerated Research – Neurological (National Stroke Foundation Inc) grant opportunity, and was awarded s47(1)(b) to:

- undertake research over 3-years from 2018-19 to develop 'living' clinical guidelines for stroke management, and
- oversee clinical research into innovative and cutting-edge treatments for young stroke survivors.

The grant agreement was executed on 23 July 2018 (Attachment C). There are two primary projects and outcomes for this grant (tied to the two dot points above, respectively), each with their own Activity Schedules. These are:

1. the 'Australian Living Guidelines for Stroke Management' project (Living Guidelines project), which aims to demonstrate improvement in stroke care by developing a model of producing trustworthy, contemporary clinical guidelines; and
2. the 'Return to Life, return to work' project (Return to Life project), which aims to support research in young stroke recovery. There were two clinical trials supported through this arm of the project, and these are:
    a. the Perispinal Etanercept to improve Stroke Outcomes (PESTO) trial; and
    b. Early vocational intervention for people after stroke: A randomised clinical trial (RTW trial).

The Australian Living Guidelines for Stroke Management project is now complete and the RTW trial, which represents the "return to work" component of the second project is on track to be completed by the current Activity Completion Date of 30 June 2023.

On 2 June 2021, the Delegate approved a formal grant variation request to extend the project by 18-months due to COVID-19 related delays to participant recruitment, ethics approval and staffing, and to unlink the final payment from the provision of final reports to allow payment within the correct financial year. Both the RTW and PESTO trial were affected by these delays to varying degrees. An Agreement of Variation was executed on 7 June 2021 (Attachment D). Key variations to the grant agreement included extension of the Activity Completion Date from 30 June 2021 to 31 December 2022 and Agreement End Date from 31 December 2021 to 30 June 2023. This variation was actioned prior to development and establishment of the MRFF Grant Variation Policy.

s47G

s47G

As the Living Guidelines project is already complete, and the RTW trial is on track to be completed by the current Activity Completion Date, the Department recommended the Return to Life, Return to Work project Activity Schedule (which includes project milestones against which progress is assessed) be split in two. This is to better reflect grant activity changes to each of the trials (PESTO & RTW) and ensure each separate trial activity progress can be monitored effectively.

Following this change, the grantee requested a further revision to the newly created RTW trial Activity Schedule, an 8-month extension to the Milestone 5 due date, to allow more time for publication decision making (Attachment H). The grantee notes however this requested change is not critical as it will not have a material impact on the completion of RTW trial activity by the current Activity Completion Date.

This request will impact on several aspects of the grant agreement, including the Activity Completion Date, milestones, and estimated expenditure across remaining financial years of the grant. One additional progress report has been added to ensure consistent monitoring of grant activity and expenditure. This request will bring the cumulative extension period for this grant to 30 months (2.5 years – 18 months approved previously, and 12 months requested), however we consider this an exception circumstance as the delays to the PESTO project were outside of the grantees control.

BGH, which is administering the grant, has advised that a Variation Contract is the appropriate mechanism for this request as the grantee has provided sufficient detail for all revised Activity Schedule changes, will likely result in project outcomes being met successfully, and is not an unexpected nor unreasonable request (Attachment I). Further, all changes are consistent with the grant opportunity outcomes and objectives outlined in section 1.3 of the grant opportunity guidelines and Clause A and B of the Grant Agreement (Attachment J).

The proposed Variation Contract (Attachment A) has been developed in response to this request and contains the following variations:

Clause C – Duration of the Grant

- Activity Completion Date extended by 12-months from 31 December 2022 to 31 December 2023
- Agreement End Date extended by 12-months from 30 June 2023 to 30 June 2024.

Clause C – Activity Schedule – "Return to life, Return to work"

- Split from one into two Activity Schedules, creating one each for the funded clinical trials:
    - A. Return to Life - PESTO Trial (Perispinal Etanercept to improve Stroke Outcomes)

- B. Return to Work - RTW Trial.

Clause C – Activity Schedule – Return to life (PESTO Trial)

- Title and descriptions revised for milestones 3, 4, 5, 6, 7, 8 & 9
- Milestone 3 due date brought forward by 3-months from 30 June 2019 to 31 March 2019
- Milestone 4 due date brought forward by 6-months from 31 December 2019 to 30 June 2019
- Milestone 5 due date brought forward by 28-months from 30 April 2022 to 31 December 2019
- Milestone 6 due date brought forward by 16-months from 30 April 2022 to 31 December 2019
- Milestone 7 due date brought forward by 12-months from 31 December 2022 to 31 December 2021
- Addition of Milestone 10, due 30 June 2023
- Addition of Milestones 11, 12 & 13, due 31 December 2023.

Clause C – Activity Schedule – Return to work (RTW Trial)

- Milestone 5 extended by 8-months from 30 April 2022 to 31 December 2022.

Clause E - Reporting

- Addition of one ad-hoc report for the period 1 January 2022 to 30 June 2022, due 31 July 2022
- Addition of one progress report for the period 1 January 2022 to 31 December 2022, due 31 January 2023
- End of project and Independent Audit report due dates extended by 12-months from 31 March 2023 to 31 March 2024.

ST2.1 Activity Budget

- Updated to account for actual expenditure and revised estimate expenditure for all financial years 2018-19 to 2023-24 (Attachment K).

In accordance with the MRFF Grant Variation Policy (D22-1096474), the variation aligns with:

- a 'Defer an in-progress grant' variation as it makes changes to Activity and Agreement dates post Activity Commencement Date.

The variation does not change the broad outcomes of the grant, and the requested changes if approved will improve monitoring of the grant.

Risk Assessment

As the COVID-19 pandemic remains ongoing, an updated Risk Management Plan has been provided by the grantee, which identifies key risks and mitigation strategies up to the proposed Activity Completion Date (Attachment B). One additional progress report has also been included in the Variation Contract to monitor project activity and expenditure, where the grantee will be required to report on all project activity including progress of recruitment for all clinical trial activities. The EPR Section is satisfied this variation will likely result in the completion of all grant activity by the proposed Activity Completion Date.

Next steps

If approved, BGH will issue a Variation Contract to the grantee. It will then be returned to you for execution.

Documentation
All relevant documentation pertaining to the proposed variation has been filed (in accordance with Corporate Business Rule 2: Records Management) in TRIM at E22-250591.

Recommendations
As the Departmental delegate and approver, under sections 26 and 27 of the Medical Research *Future Fund Act 2015* (MRFF Act), that you:

1. **APPROVE** the proposed Variation Contract at Attachment A, providing a defer-in-progress request for the National Stroke Foundation to undertake research activities under the grant agreement for the 'Australian Living Guidelines for Stroke Management and "Return to life, Return to work" – A targeted clinical research investment in stroke recovery for young survivors' project providing a: a. 12-month extension to the Activity Completion Date from 31 December 2022 to 31 December 2023 b. 12-month extension to the Agreement End Date from 30 June 2023 to 30 June 2024.	**1. Approved ~~/ Not Approved~~**
2. **NOTE** that a Variation Contract is the appropriate mechanism for the proposed variation as it prompts numerous changes to the content of the original agreement, which are described in the **Background**	**2. Noted ~~/ Please Discuss~~**
3. **NOTE** that the Variation Contract applies to three variation types as per the MRFF Grant Variation Policy: a. a 'Defer an in-progress grant' variation as it makes changes to Activity and Agreement dates post Activity Commencement Date	**3. Noted ~~/ Please Discuss~~**
4. **NOTE** that the proposed variation includes revised Activity Completion and Agreement End dates, milestones, reporting schedule, and Activity Budget	**4. Noted ~~/ Please Discuss~~**
5. **NOTE** that an updated Risk Management Plan has been provided by the grantee which identifies key risks and mitigation strategies up to the proposed extended Activity Completion date (Attachment B)	**5. Noted ~~/ Please Discuss~~**
6. **NOTE** that that if you approve, the Business Grants Hub (BGH), which is administering the grant, will: a. issue the Variation Contract to the grantee for signing, and once signed it will be returned to you for execution b. advise the grantee that if they require a further extension to the grant activity that they will be required to demonstrate exceptional circumstances in line with the MRFF Grant Variation Policy.	**6. Noted ~~/ Please Discuss~~**

[Authorised electronically]
Dr Masha Somi
Chief Executive Officer
Health and Medical Research Office
17 October 2022

Attachments:

A. Draft Variation Contract
B. Updated Risk Management Plan
C. Grant agreement
D. Agreement of Variation (June 2021)
E. Ad-hoc progress report
F. Grant variation request
G. PESTO Project Plan
H. Grant variation request (RTW trial, Milestone 5)
I. BGH Advice
J. Grant Opportunity Guidelines
K. Activity Budget.

Contact officer: s22
Phone:
E/A Corro Ref: N/A
TRIM ref: D22-2554780

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 s47(1)(b) .
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.

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)	Dr Masha Somi
Position (print)	CEO, Health and Medical Research Office
Signature and date	Masha Somi Digitally signed by Masha Somi Date: 2022.10.28 17:46:27 +11'00'
Witness name (print)	s22 HEALTH AND MEDICAL RESEARCH OFFICE
Signature and date	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)	s47F
Capacity of authorised representative (print)	PRESIDENT
Signature and date	s47F 24/10/2022
Witness name (print)	EXECUTIVE ASSISTANT
Signature and date	s47F 24/10/2022

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

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

B. Return to Work

No.	Title and description	Due date
1		
2		
3		
4		
5		
6		
7		
8		
9		

S22

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.

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:

Eligible expenditure item	Actual expenditure 2018-19	Actual expenditure 2019-20	Actual expenditure 2020-21	Actual expenditure 2021-22	Estimated expenditure 2022-23	Estimated expenditure 2023-24	Total
Contract Expenditure	s47(1)(b)						
Labour costs							
Travel costs							
Other eligible expenditure							
Total							

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

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.

Australian Government
Department of Industry, Science and Resources

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Department of Industry,
Science 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: **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:

s22

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

- s22

- 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.

Issues:

S22

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 s22 on s22

Kind regards

s22

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

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

9 August 2022

s22
Program Management and Delivery
Business Grants Hub
Department of Industry, Science, Energy and Resources

Sent via email: arp@industry.gov.au

Dear s22

RE: APPLICATION ID EPCD000019 (ARG73055)

Thank you for your email dated 28 June 2022 confirming that a variation 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.

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

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The ad-hoc report for "*Return to life, return to work" - a targeted clinical research investment in stroke recovery for young survivors* – for the period 1 January 2022 to 30 June submitted through the Business Grants Hub portal on 29 July 2022 further supports the rationale for this variation request.

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 or phone 03 9918 7204.

Sincerely,

s47F

Stroke Foundation

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

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	s47F (National Stroke Foundation) Professor Vincent Thijs (Return to life PESTO) s22
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 s22
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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Department of Health and Aged Care

Medical Research Future Fund

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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%
Comments: As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
Comments: As previously reported on 29/07/2022.			
3. Successful applicant engaged	31/03/2019	18/03/2019	100%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
s47G			
8. Establishment of Data Safety and Monitoring Committee and its Charter is finalised	31/12/2022	31/12/2022	100%
Comments: 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%
Comments: As previously reported on 31/01/2023.			
10. Publication of study protocol and statistical analysis plan	30/06/2023	01/04/2024	100%
s47G			
11. Patient recruitment concludes	31/12/2023	24/12/2023	100%

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

Milestone/Objective – A. Return to life PESTO	Agreed End Date	Actual/Anticipated End Date	Current % Complete
Comments: 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%
s47G			
13. Project end date	31/12/2023	31/12/2023	100%
Comments: 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.			

s22

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

s22

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)*

s22

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)

s22

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

s22

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)*

s22

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)

s22

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Department of Health and Aged Care

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s22

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.

s22

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. s47G . 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)

Australian Government
Department of Health and Aged Care

Medical Research Future Fund

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)*

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.

(A) Expenditure Item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period [1.01.2023-31.12.2023] (AUD)	(D) Total actual expenditure (AUD)	(E) Comments
Contract expenditure	s47(1)(b)			
Labour costs				
Travel costs				
Other eligible expenditure				
TOTAL				

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.

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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.

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)

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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,	Living clinical guidelines for stroke: updates, challenges and opportunities	The Medical Journal of Australia	DOI: 10.5694/mja2.51520

	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	-

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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	https://doi.org/10.1177/23969873241249248

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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)

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 future MRFF funding opportunities. (min 200, max 300 words)

B. Return to work

Nil.

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.

- Financial year completed: 31 December 2023
- Sales revenue (turnover): s47(1)(b)
- Export revenue: $0
- R&D expenditure: s47(1)(b)
- Taxable income: $0 - tax not applicable
- Number of employees including working proprietors and salaried directors (headcount): 98
- Number of independent contractors (headcount): 0 (as at 31 December 2023)

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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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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	s47F (National Stroke Foundation) Professor Vincent Thijs (Return to life PESTO) s22
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 s22
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%
Comments: As previously reported on 29/07/2022.			
2. Call for research applications concludes	31/12/2018	30/11/2018	100%
Comments: 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
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: 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%
Comments: Not applicable			
13. Project end date	31/12/2023	31/12/2023	0%
Comments: Not applicable			

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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)*

s22

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)

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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)

s22

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).

The team have, as outlined in point 7 above, different strategies to achieve complete recruitment by the end of December 2023. s47G

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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)

s22

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)

s22

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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)

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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.

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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)*

A. Return to life PESTO

As the trial results are still pending, implementation of this unproven therapy is not yet required. As the trial is a phase 2 trial, a definitive trial would be required including health economic analysis to apply for registration and reimbursement, presupposing that PESTO will be a positive trial. Nevertheless, some physicians and patients may elect to proceed with off-label treatment based on positive PESTO trial results. It will be important to present the results of the trial in a cautious way so that the public and treating stroke doctors understands the stage of research with PESTO and the regulatory status. If the trial demonstrates a harmful effect, it is important that the health authorities be advised and the public informed of this. We have currently no indication of any untoward effect, but this is best gauged upon the totality of the trial.

Work in 2023 will be focused on disseminating the results upon completion of the trial. This will be done through presentation at (inter)national conference(s), publications in major international journals, press releases and other social media. Stroke Foundation communicates via social media channels and its digital platforms (including EnableMe) to the target audience.

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)*

s22

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s22

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.

(A) Expenditure Item	(B) Approved Budget (AUD)	(C) Actual expenditure for this period (AUD)	(D) Total expenditure to date (AUD)	(E) Estimated expenditure for next period (AUD)	(F) Comments
Contract expenditure	s47(1)(b)				
Labour costs					
Travel costs					
Other eligible expenditure					

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	s47(1)(b)
TOTAL	

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.

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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)

s22

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.

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
s22

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. s22

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. s22
5. Publication of study protocol and statistical analysis plan	30/04/2022	**PESTO** – 30/06/2023 s22	**PESTO -** 95% - Study protocol 70% - statistical analysis plan s22	Commentary addressing specific queries raised by the Department of Health is provided in Q3.
6. Patient recruitment concludes	30/04/2022	**PESTO -** 30/09/2023 s22	**PESTO -** 52%	**PESTO** – 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. s22
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. **PESTO** - 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%	**PESTO** – Not started and pending variation request. s22
9. Project end date	31/12/2022	31/12/2023	45%	*Pending project duration variation request*

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

Whilst recruitment has been steady, recruitment has been slower than anticipated, so that if an extension is not granted and the trial were to finish by the end of 2022, there would be a major risk for successful completion of the PESTO trial. The team would have to report inconclusive data, based on an insufficient number of patients, which will not help the stroke community to understand the role of this potential unproven treatment.

The team have taken the following actions to maintain and increase recruitment at a steady level:

- s47G
- expanded the recruitment strategy by regular mailings using the Australian Stroke Clinical Registry and close collaboration with the Stroke Foundation's channels with clinicians (InformMe) and patients (EnableMe).
- the research team have asked the participants to contact their peers through stroke survivor communities.

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.

s22

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 <u>overall</u> 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.*

<u>PESTO</u>

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.

s22

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.

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	s47(1)(b)		

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	s47(1)(b)

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.

s22

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.

s22

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.

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
s22

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. s22

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. s22
5. Publication of study protocol and statistical analysis plan	30/04/2022	PESTO - 31/12/2022 s22	70%	PESTO – Study protocol (21/01/2022), submission for publication planned for May 2022. Statistical analysis plan to be finalised in September 2022. s22
6. Patient recruitment concludes	30/04/2022	PESTO – 15/09/2022 s22	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. s22
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 2nd 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 9th 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.

s22

s22

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 <u>overall</u> 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 15th September 2022.

s22

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.

s22

s22

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
Labour costs	s47(1)(b)		
Contract expenditure			
Travel Costs (domestic)			
Materials			
Other eligible expenditure			
Total Project costs			

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.*

All expenditure to date has been in accordance with the approved project activity budget. As a result of the contract extension, Stroke Foundation's contribution to Living Guidelines has increased by s47(1)(b) to support continuing delivery of the Living Guidelines program.

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	s47(1)(b)

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.

s22

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.

s22

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.

31 March 2021

s22
Program Management and Delivery
Business Grants Hub
Department of Industry, Science, Energy and Resources

Sent via email: arp@industry.gov.au

Dear s22

RE: Application ID EPCD000019 (ARG73055)

Thank you for your email dated 22 March 2021 requesting elaboration on the following items, in relation to our formal contract extension request and additional information for the Progress Report 3 submitted in January 2021.

1. We **confirm** that the total eligible expenditure incurred under the project is s47(1)(b) (as reported in Progress Report 3), that is from start of the project until 31 December 2020.
2. The forecasted eligible expenditure from 01 Jan 21 to 30 Jun 21 is s47(1)(b).

   New budget table for 01 Jan 21 to 30 Jun 21 and 01 July 21 to 30 Jun 22:

	Total	Guidelines	Research
Total Grant	s47(1)(b)		
Spent			
Balance as at 31 Dec 2020			
Jan 21 - Jun 21			
Jul 21 - Jun 22			
Total Jan 21 - Jun 22			

3. As the project requires an additional year to complete, you have advised that a further s47(1)(b) will be required to manage the project. If this shortfall cannot be found from other sources, what project activities may be impacted, for example you may reduce clinical trials participant from 200 to 150. Also, please explain if and what influence the reduction in project activities and scope will have on the overall objectives of the project, any dire consequences.

Stroke Foundation was in regular contact with our research teams since the onset of the coronavirus (COVID-19) pandemic to understand the impacts on these projects and consider the risk mitigation strategies to ensure the deliverables can be met.

The COVID-19 response and lockdown measures implemented across States and Territories from March 2020, and recognising survivors of stroke are among those most vulnerable to COVID-19, resulted in mass suspension of clinical trial recruitment, particularly affecting stroke studies and hospital-based sites. For the Melbourne-based trial sites requiring some face-to-face interaction with trial participants, restrictions on this activity stretched between March and October 2020 in Australia.

For the PESTO trial, the severity of the COVID-19 pandemic's impact in the international (UK) trial site has meant that ethics approval for this site has not yet been achieved. The UK trial site has confirmed their commitment to gaining ethics and governance approvals and this is likely to be achieved within the revised timeline, anticipated in the second half of 2021. The UK site has already identified 20 trial participants once the site is approved to commence.

To mitigate the risk of reduced clinical trial participants due to COVID-19's impact, the PESTO trial research team onboarded a new trial site located in New Zealand in 2020, given this country's effective management of COVID-19 cases and the efficiency of their ethics review system. The NZ site was able to achieve several activities quickly, including the onboarding and training of staff from December 2020 to January 2021, securing ethics approval in February 2021 and completing the enrolment of ten participants by March 2021.

Both clinical trials have required a revised timeline extension, the maximum being an extension of 12 months. At the time of report submission (Progress Report 3, January 2021), the projected budgetary impact for the PESTO trial was estimated at s47(1)(b) attributable to personnel costs to enable project oversight for the period from 01 Jul 2021 to 30 Jun 2022.

Subsequent to further discussions with the PESTO research team and an analysis of per patient costs based on the active trial sites (Austin Health in Melbourne and the New Zealand site), a reallocation of the **original project budget to deliver the project objectives by 30 Jun 2022 is enabled via the following means**:

- Per patient actual costs are on average s47(1)(b) than originally budgeted for. This budget saving for the 168 recruitment target equates to s47(1)(b) for **budget reallocation to cover personnel and any additional costs to support a timeline extension from 01 Jul 2021 to 30 Jun 2022.**

Project activities and scope (PESTO)

- The **scope of international trial sites has been expanded to include the NZ site in addition to the UK site.**
- **The recruitment target of 168 remains feasible with a 12 month project extension to 30 June 2022, based on each active site enrolling on average a minimum of 4 participants each month between April 2021 and April 2022 (1 participant enrolled per week per site).** As noted above, the UK site has currently identified 20 trial participants. Monthly recruitment reports are now provided to Stroke Foundation by the PESTO research team.

Project activities and scope (Return to Work)

- **The feasibility of the intervention and trial design is well supported and this will be the main achievement of this project**, irrespective of whether it is able to attain the original sample size target of 54 participants.
- Recruitment as at January 2021 was 16. **With an additional 6 month project timeline, in scope to deliver with the original budget, anticipated recruitment = 30 (minimum) which will deliver on the project's objectives.**
-

4. Milestones and activities from 01 Jul 21 to 30 Jun 22.

No.	Milestone – Title and Description	Due Date
10	Publication of study protocol & statistical analysis plan	30/04/2022
12	Patient recruitment concludes	30/04/2022
14	Finalise Data Safety & Monitoring committee	30/06/2022
16	Clinical trial close out	30/06/2022
18	Project end date	30/06/2022

Reporting

Report type	Period start date	Period end date	Agreed evidence	Due Date
Progress – Return to life, return to work	1 January 2021	31 December 2021	Satisfactory completion of progress report in portal	31 January 2022
s22				
End of Project - Return to life, return to work	Project start	30 June 2022	Satisfactory completion of final report in portal	28 Sept 2022
Independent Audit Report - total	Project start	30 June 2022	Satisfactory report completed by independent auditor	28 Sept 2022
s22				

Thank you for your support and consideration of this formal extension request. Please don't hesitate to contact us if any further information is required.

Yours sincerely,

s47F

Executive Director Stroke Services
Stroke Foundation

Application EPCD000019

Report Summary

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
s47F

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

002 - Project start date - Return to life, Return to work

Description
Contract executed and project commences

Expected End Date
30/07/2018

Actual End Date
30/07/2018

Current % Complete
100

Progress Comments

Agreed End Date
30/06/2021

Previous % Complete
0

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

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

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

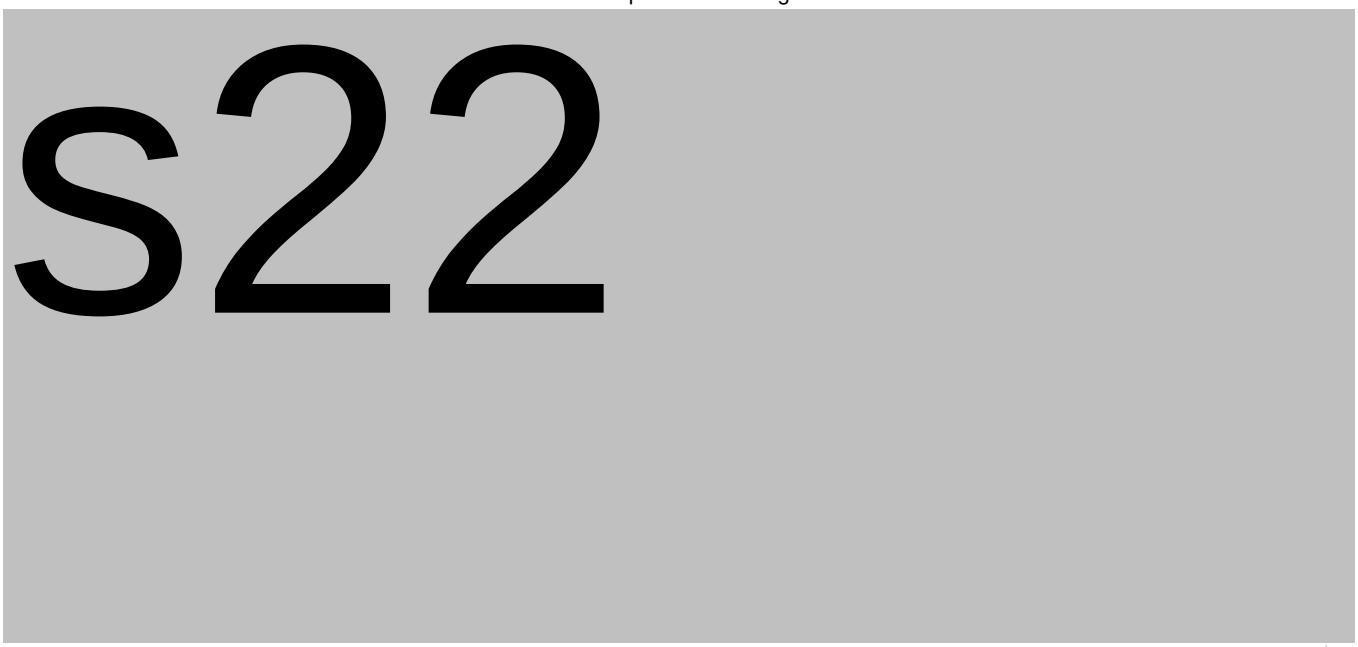
Current % Complete
15

Progress Comments
PESTO - 5 patients enrolled in 2020 (Nov-Dec). RTW - COVID-19 impact: Recruitment was slower from May 2020 with a reduction in patients presenting to hospital with stroke; the trial was formally paused in August 2020 due to the release of the DoH (Vic) research advice and in accordance with the Alfred Health Contingency Plan for COVID1 Interruption to Clinical Trials (Attachment 3) and following written approval, the project recommenced recruitment in December 2020. Strategies employed to address impact: Trial was approved for telehealth consent and telehealth (hybrid) delivery following an ethics application. This allowed some trial activity when hospital access, permissions for staff to visit participants in the community and in PPE in accordance with permissions granted by Alfred Health and DoH (Vic) COVID19 policies and recommendations. The research team have also applied for and received ethics approval to add a second recruitment site (Eastern Health) for 2021.

Agreed End Date
30/06/2021

Previous % Complete
0

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. RTW - DSMC established 15/10/2019, 02/11/2019.

Agreed End Date
30/06/2021

Previous % Complete
0

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.
RTW - Request extension of 6 months due to COVID impact on hospital recruitment for stroke within trial location- Greater Metropolitan Melbourne.

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

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.
s22

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 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). The budget impact is estimated at s47(1)(b) for these items between 30/06/2021-30/06/2022. 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 being 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

s22

Project expenditure

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

Head of Expenditure	Cost Type	Financial Year	Agreed project budget	Expenditure approved prior to this reporting period	Expenditure claimed in this reporting period	Expenditure claimed to date	Estimated expenditure for next reporting period [23/07/2018-29/05/2021]	Estimated total project expenditure
Project expenditure								
	Contract Expenditure							
		2018/19						
		2019/20						
		2020/21						
	Domestic travel							
		2018/19						
		2019/20						
		2020/21						
	Labour costs							
		2018/19						
		2019/20						
		2020/21						
	Materials							

s47(1)(b)

Head of Expenditure	Cost Type	Financial Year	Agreed project budget	Expenditure approved prior to this reporting period	Expenditure claimed in this reporting period	Expenditure claimed to date	Estimated expenditure for next reporting period [23/07/2018-29/05/2021]	Estimated total project expenditure
		2018/19	s47(1)(b)					
		2019/20						
		2020/21						
	Other eligible expenditure							
		2018/19						
		2019/20						
		2020/21						
	Plant and equipment							
		2018/19						
		2019/20						
		2020/21						
Total								

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 s47F , 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

Additional documents

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

Report Declaration

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

For Official Use Only

Australian Government
Department of Industry, Innovation and Science

Business

Medical Research Future Fund- Accelerated Research

Progress Report

Submit your completed report to arp@industry.gov.au

Grantee name	National Stroke Foundation
Project title	s22 and 'Return to life, return to work' - a targeted clinical research investment in stroke recovery for young survivors
Project number	ARG73055 (MRFF-N-SF)
Reporting period	01/01/2019 to 31/12/2019

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.

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
s22				

Australian Government
Department of Industry, Innovation and Science

Business

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
s22				

Australian Government
Department of Industry, Innovation and Science

Business

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
s22				

Australian Government
Department of Industry, Innovation and Science

Business

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
s22				
RETURN TO LIFE, RETURN TO WORK PSE: Perispinal Etanercept to improve Stroke Outcomes (PESTO) s22				
Call for research applications concludes - Return to life	31/12/2018	30/11/2018	100%	

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
Trial endorsement - Return to life, return to work	30/06/2019	**PSE:** ASTN endorsement 28/06/2019 (Att 3); Ethics approval 5/09/2019 (Att 4); ANZCTR registration submitted. Governance 31/01/2020.	ASTN - 100% Ethics – 100% Governance 85%	Human Research Ethics Committee (HREC) approval of the trial by Austin Health on 5 September 2019. Austin Research Governance Office was submitted on 24 September 2019 and is pending approval.
		s22		
Staff training concludes - Return to life, return to work	31/12/2019	**PSE:** 28/02/2020	0%	To be performed at Site Initiation Visit anticipated in February 2020.
		s22		
Publication of protocol & plan - Return to life, return to work	31/12/2020	**PSE:** 30/04/2022	0%	
		s22		
Patient recruitment concludes	31/12/2020	**PSE:** 31/12/2021	10%	Delay of trial initiation has extended this milestone by the equivalent period of one year.

Milestone	Agreed end date	Actual/ anticipated end date	Current % complete	Progress comments – include progress towards completion of agreed project activities including risks arising, how they are being managed to ensure planned project outcomes are met and any delays in achieving Milestones
		s22		
Finalise Data Safety & Monitoring committee	30/06/2021	**PSE:** DSMC established 15/10/2019	50%	The Data Safety and Monitoring Committees (DSMC) for the trials have been established and will extend until project completion.
		s22		
Clinical trial close out - Return to life, return to work	30/06/2021	**PSE:** 30/06/2022	0%	One year extension requested.
		s22		

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

s22

s22

c. Is the overall project proceeding in line with your project plan and grant agreement? s22

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

RETURN TO LIFE, RETURN TO WORK

PSE: Issues delaying project timelines have now been resolved. The trial is expected to commence recruitment in early February 2020. The research team will attempt to make up time during the recruitment process.

s47G

s22

s22

d. 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. Project outcomes

a. Outline the extent to which you have met the project objective[s] to date:

a. The objectives of this grant opportunity are to support neurological research.

s22

RETURN TO LIFE, RETURN TO WORK

The first year for the trials has been largely dedicated to achieving the milestones of ethics and governance approvals. Both trials are in the early stages with their recruitment.

b. Outline the extent to which you have met the project outcome[s] to date:

a. 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.

s22

s22

RETURN TO LIFE, RETURN TO WORK

Both trials are in the early stages with their recruitment.

c. Are you on track to deliver these project objective[s] and outcome[s]?

s22

RETURN TO LIFE, RETURN TO WORK

PSE: Request of a one-year extension to deliver the project objectives and outcomes per revised timelines, as provided in the milestone table.

s22

d. Provide information about your progress against your project milestones.

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

s22

RETURN TO LIFE, RETURN TO WORK

PSE: Trial milestones completed include finalisation of protocol, informed consents (refer Attachments 5 and 6), Australasian Stroke Trials Network (ASTN) endorsement, submissions to Human Research Ethics Committee and Research Governance Office. Achieved ASTN endorsement and HREC approval.

s22

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

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

s22

RETURN TO LIFE, RETURN TO WORK

No preliminary findings at this early reporting stage.

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

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

s22

RETURN TO LIFE, RETURN TO WORK

PSE: N/A at this early reporting stage.

s22

3. Eligible expenditure summary

a. Complete the following table to show information about your eligible project expenditure. Eligible expenditure is divided into the same categories as the budget in your application

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 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 [2018]	s47(1)(b)
ii. Eligible expenditure incurred this reporting period [2019]	
iii. Estimated expenditure for next reporting period [2020]	
iv. Estimate for remaining reporting periods in current financial year (if applicable) [Jan 2020-Jun2020]	
v. Estimated total expenditure for future financial years [2021]	
vi. Total estimate for project (i + ii + iii + v)	

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.

4. Attachments

a. Attach any agreed evidence required with this report to demonstrate project progress.

1. Letter confirming NHMRC CEO approval of the amended recommendations in the Clinical guidelines for stroke management.
2. Stroke Foundation Media Release - Return to Life, Return to Work research grants announced.
3. Letter confirming ASTN endorsement of the PESTO trial.
4. Austin Health HREC approval of the PESTO trial.
5. Austin Health HREC approved Participant Information Sheet/Consent Form for the PESTO trial (Master)
6. Austin Health HREC approved Person Responsible Information Sheet/Consent Form for the PESTO trial.
7. Alfred Hospital HREC approval for the Return to Work trial.
8. Letter confirming ASTN endorsement of the Return to Work trial.
9. Alfred Health approved Participant Information Sheet for the Return to Work trial.
10. Knowledge Dissemination and Transition Plan for the Return to Work trial.
11. s47G [redacted]

b. Attach copies of any published reports and promotional material, relating to the project.

12. Return to Work trial registration: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=378112&isReview=true

Australian Government
Department of Industry, Innovation and Science
Business

5. Certification

I, s47F , 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 and the expenditure incurred 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 . s47F ..... Date 30/01/2020

s47F

Chief Executive Officer
Stroke Foundation

Progress Report

Accelerated Research program

Submit your completed report to arp@industry.gov.au

Grantee name	National Stroke Foundation
Project title	1. s22 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.

s22

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s22

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.

s22

Page 2 of 59

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

Call for research applications

Following the public announcement of the MRFF's "Return to life, return to work" research package on 6 October 2018, the call for applications opened on 8 October 2018 to address this topic including proposals for (1) trialling Perispinal Etanercept (PSE) in chronic stroke; and (2) an intervention designed to improve return to work (RTW) rates for younger stroke survivors in Australia.

The Stroke Foundation Research Advisory Committee developed the instructions to applicants and grant documentation (attachments 2-7) to ensure appropriate guidelines are met.

The call for applications was promoted widely through professional networks in Australia and internationally, utilising the Stroke Foundation's websites and social media channels. A media release was distributed to the Stroke Foundation's media contacts and universities (attachment 8) and electronic direct mail (attachment 9). Communications were targeted to stakeholders including:

- Australian Stroke Coalition.
- Stroke Society of Australasia.
- UK Stroke Association.
- World Stroke Organization.
- Database of research grant applicants and institutional contacts.
- Stroke Foundation panel of research grant peer reviewers.
- Stroke Foundation's Board and Committee members.
- Stroke Foundation's InformMe (health professional website) members.

Applications were open for eight weeks and closed on 30 November 2018. The total applications received were:

- PSE applications – Two (2).
- s22

The Research Advisory Committee completed a preliminary eligibility review of applications in December. s22

Invitations to review the applications were extended to the Stroke Foundation's existing pool of independent peer reviewers and recommended international experts in clinical trials. For each scheme, 31 potential reviewers were invited (62 in total). The Stroke Foundation adheres to a strict no conflicts of interest policy (attachment 10) for review of research grant applications. Each eligible application was reviewed by five independent expert reviewers with no conflicts with the applicants. A total of 13 reviewers were allocated for this review in December 2018. The review panel (5) for the PSE applications consists entirely of international experts engaged during this call for applications (attachment 11). Collation of the completed reviews is expected by 30 January 2019.

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The Research Advisory Committee will meet on 22 February 2019 to discuss the outcome of the independent review process and make recommendations to award funding to the top ranked proposals under each grant (PSE and RTW). Following this recommendation, applicants will be advised of the outcome of their application, be required to acknowledge acceptance of the grant and the Terms and Conditions of reporting and acquittal. Once signed acknowledgment is received back to the Stroke Foundation, the unsuccessful applicants will be informed of the outcome. We anticipate that we will be able to publicly announce successful grant recipients by the end of February 2019.

The Stroke Foundation has recorded interest received from the stroke survivor community to participate in the trials and will work with the successful research teams to facilitate a process for consumers who have expressed an interest in this research to be considered for participation (subject to trial applicability).

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.

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

Att 2_2019 Return to life_Return to work Research Grants Application Guide

Att 3_Clinical Trials Conditions of Research Grant Award

Att 4_2019 Perispinal Etanercept Clinical Trial Grant Application Form

Att 5_2019 Return to Work Clinical Trial Grant Application Form

Att 6_Perispinal Etanercept Grant 7 Point descriptor scale 2018

Att 7_Return to Work Grant 7 Point descriptor scale 2018

Att 8_20180610_MEDIA RELEASE_Recovery research boost

Att 9_EDM _Applications now open

Att_10_GV006 PO Conflict of Interest Policy

Att_11_International Review Panel_PSE

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Stroke Foundation's webpage for the MRFF Clinical Research grants (as at January 2019)
https://strokefoundation.org.au/What-we-do/Research/Research-grants/Clinical-trials

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.

s22

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

The call for applications and allocation of reviewers was completed December 2018.

Note: While the project's start date was July 2018, the call for applications was delayed pending a media release by the Office of the Minister for Health (Hon. Greg Hunt MP) announcing the Accelerated Research Grant funding for this process. This announcement was made 6 October 2018.

The call for grant applications opened on 8 October 2018 and allowed enough time for applications (eight weeks), and peer review (four weeks), which has fallen over the Christmas and New Year holiday period. There is some possibility that the next project milestone may be delayed due to its comprehensive nature, that is, the endorsement of the successful project team clinical trials by the Australasian Stroke Trials Network, ethics and governance approval and trial registration by 30 June 2019. However, the research teams are aware of the project timings as included in the instructions to applicants, and will be working towards meeting the June 2019 milestone.

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.

Page 6 of 59

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

The Australian Government can choose to announce individual grant recipients at its discretion in partnership with Stroke Foundation and the successful researcher institutions.

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	s47(1)(b)
i. Eligible expenditure incurred this reporting period [2018]	
ii. Estimated expenditure for next reporting period [2019]	
iii. Estimate for remaining reporting periods in current financial year (if applicable) [Jan 2019-Jun 2019]	
iv. Estimated total expenditure in [2019-2020]	
v. Estimated total expenditure in [2020-2021]	
vi. Total estimate for project (i+iii+iv+v)	

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.

Not applicable as the forecast expenditure for the years 2019-2021 is being reported for the first time. Refer clause 2a above.

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

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

4. Certification

I, s47F 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 s47F ..... Date 29/01/2019

s47F

Chief Executive Officer
Stroke Foundation

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Return to life, return to work Clinical Research Grants Application Guide

ATTACHMENT 2

1. Introduction

This Application Guide serves to outline the overarching funding rules of the 'Return to life, return to work' Clinical Research Grants facilitated by the Stroke Foundation. This document should be read before completing an application form.

2. Targeted Clinical Research

Supported by the Australian Government's Medical Research Future Fund (MRFF), the Stroke Foundation will facilitate a targeted clinical research investment in stroke recovery for young survivors through two dedicated research grants funded from 2019-2021:

- **Clinical Trial: Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age)**
- **Clinical Trial: Return to work (RTW) for younger stroke survivors in Australia.**

3. Purpose

The 'Return to life, return to work' initiative will fund projects aimed at developing innovative recovery and rehabilitation clinical interventions for younger stroke survivors in Australia - an emerging priority area with unmet needs. These projects will continue to accelerate important neurological research and support Australian researchers to be at the forefront of finding solutions for stroke recovery.

4. Critical dates

Stage	Date
Applications open	**8 October 2018**
Applications close	**5pm AEDT Friday 30 November 2018 (daylight savings time)**
Advice to applicants	**February 2019**

5. Endorsement of Clinical Trials

All clinical trials facilitated by the Stroke Foundation **must** align with Australasian Stroke Trials Network (ASTN) guidelines, and meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable[1].

1 Kwakkel G, et al. Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabil Neural Repair. 2017;31:793-799

Return to life, return to work Clinical Research Grants Application Guide

6. Eligibility Criteria

6.1 Clinical Trial: Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age)

A 2.5-year grant of up to s47(1)(b) to support a robust, independent, multi-centred clinical trial of Perispinal Etanercept (PSE) in Australian stroke survivors of working age.

Who may apply?

- Researchers of any career stage may apply.
- The research team must be Australian led.
- International trial sites may be included in the project.
- Lead applicants who have (or have not) previously received a research grant from the Stroke Foundation are eligible.

What may be funded?

- The research plan must follow the specifications detailed in Section 7 application procedure for clinical trials.
- A significant part of the research must be carried out in Australia.
- Preference will be given to those applications including some, or all, of the following criteria:
  - i. Have significant community engagement
  - ii. Have international collaboration particularly with funding contribution.
  - iii. Applications that follow the CONSORT[2] criteria and TIDieR guidelines[3].
- The grant is to be used for direct research costs such as equipment and, support personnel such as research assistants or casual help, or other assistance necessary for a specific project.

What is not funded?

- This funding does not cover institutional fees; infrastructure costs; overheads; PhD stipends.

2 http://www.consort-statement.org/

3 Better Reporting of Interventions: Template for Intervention Description and Replication (TIDieR) Checklist and Guide Hoffman et al. BMJ 2014

Return to life, return to work Clinical Research Grants Application Guide

7. Application procedure

This Return to work, return to life Clinical Research Grants Application Guide should be read before completing an application form. Application forms are available on the Stroke Foundation website: https://strokefoundation.org.au/clinicaltrials

All applicants are required to use the application template and adhere to length and formatting requirements in the table below and in the application form. Any applications not using the template will be deemed **ineligible**. All details included must be current at the time of the application close date.

Formatting Component	Requirement
File format	PDF
Page size	A4
Page margin	1.7cm left and right margin, 2.5cm top and bottom margin
Page limits	Page limits vary between parts of the application. Refer to the relevant advice and instructions to applicants for applicable page limits.
Font	Arial Size 11
Line spacing	Single

The application form should contain all information necessary for assessment by the review panel, either by reference to published work or by including the essential components as outlined below:

Section	Component	Response Limit	Properties
1.1.	Project Summary	Half page	Outline the research question, methodology and significance of the project
1.4.	Research Team	As required for up to 10 Chief Investigators (CI)	
2.1. - 2.5.	Research Proposal	9 pages	A detailed outline of the research plan that includes: 2.1. Background and Rationale 2.2. Research aims and Hypotheses 2.3. Detailed research plan 2.4. Sample Size Justification and Statistical Analysis 2.5. Project outcomes and Significance
2.6.	Timeline and Milestones	As required for up to 10 milestones, with a heading and two sentence description	There are 6 mandatory milestones provided in the application template. These must be incorporated into the research proposal timeline.
3.1.	CI Track Record including the Top 5 publications in the last 5 years	Up to 2 pages per CI	A track record summary, since 2014, for each Chief Investigator that is relevant to the application and relative to opportunity and career stage. Include details of career

Return to life, return to work Clinical Research Grants Application Guide

			disruptions in this section. The following areas should be considered: • top 5 publications in the past 5 years relevant to the application • career summary including qualifications, employment and appointment history • research support including grants and fellowships • contribution to field of research which may include the impact of previous research including translation and commercialisation • collaborations • community engagement and participation • professional involvement including committees, conference organisation • international standing including invitations to speak, international committees • supervision and mentoring • peer review involvement including granting organisations, manuscripts, editorial responsibilities • industry relevant expertise and output • other information you think is vital to your application.
3.2.	Publication Track Record for Chief Investigators	Attach as a separate document as required for CIs only, since 2014	Group publications by type (original articles, reviews, editorials, letters to the editor, book chapters, books). Exclude published abstracts from this list.
3.3.	Summary of Team Quality & Capability, including how the team will work together	Up to 1 page	The team must be Australian led, but international investigators may be included in the research team. Their contribution should be highlighted and practicalities of their involvement explained.
4	Project Budget & Justification	As required	Detail for each budget item, on a yearly basis with full justification.
5	References	As required	A full list of references cited in the application.
6	Certifications	1 page	Certification required by the Chief Investigator A (Applicant) and Head of Department in the administering institution/research body.

Research Proposal - 9 pages

Clinical trial proposals must have a research plan that:

- Is well-defined, highly coherent and strongly developed.
- Is based on a clearly defined and robust scientific rationale.

- Has a near flawless study design that is sham-controlled, multi-centred and includes blinding of participants and outcome assessors.
- Has a clearly defined, pre-determined and accepted functional outcome measure, with assessment of neurological recovery by a team independent of the intervention team.
- Has a sample size that is based on quality randomised data that includes feasibility for recruitment timelines.
- Adheres to industry standards including oversight by an independent data safety and monitoring committee that includes membership by neurologists/stroke specialists, rehabilitation/recovery specialists, and a biostatistician.
- Has a registered protocol and statistical analysis plan that is published, prior to unblinding of the data.
- Has a plan for open data access once the study is complete.
- Is highly feasible with all of the required expertise, research tools and techniques established.
- Has all conflicts of interest declared and is independent from the sponsor.
- Has personnel that are all GCP certified (Good Clinical Practice).
- Is highly competitive with the best, similar research proposals internationally.
- Is aimed at a Phase 2b, including a pathway for new indication by the Therapeutic Goods Administration (TGA).
- Has an accepted primary outcome measure in the field of stroke recovery that could theoretically meet TGA approval if confirmed in a large study – provided there was evidence demonstrating the need for a larger study (with the exception of clinical trials that do not involve therapeutic goods).

8. Submission

All applications must be signed and submitted via email to research@strokefoundation.org.au by the closing date and time. Late submissions will not be considered.

Submitted applications will receive a return email acknowledgement from the Stroke Foundation. Please ensure you have received this acknowledgement prior to the deadline.

We understand that situations arise at the last minute that can delay applications. For this reason, we encourage applicants to submit your application at least a day ahead of the deadline. Please be aware that the Stroke Foundation will **not** allow extensions and will **not** allow any applications after the deadline. This includes any IT issues that arise during the submission process. We recommend that you confirm with your research administration office the timing required for certification and the procedure for submission.

Any applications received after the deadline will be deemed ineligible. This ensures an equitable process for all applicants. For queries or to confirm receipt contact research@strokefoundation.org.au or phone s47F .

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9. Outcome of application

The Stroke Foundation will advise applicants and their institutional contact via email of the outcome of their submission by February 2019.

10. Approvals to be obtained prior to funding commencing

As per Section 5, the research undertaken must conform to the principles set out by the NHMRC's Statement on Ethical Conduct in Human Research (2007) and The Australian Code for the Responsible Conduct of Research and any other conditions required by Human Research Ethics Committees. The research undertaken must align with Australasian Stroke Trials Network (ASTN) guidelines, and meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable[1].

Funding will not be released to the nominated institution until all relevant approvals, particularly in relation to ethics and governance, have been received and lodged with the Stroke Foundation prior to the commencement of the research.

11. Consumer and community participation

Researchers are encouraged to consider the benefits of actively engaging consumers in their proposed research. Applicants should refer to The Consumer Health Forum of Australia Inc. and NHMRC Statement available at: http://www.nhmrc.gov.au/guidelines/publications/r22-r23-r33-r34

If you would like your research study listed on the Stroke Foundation website to recruit consumers from our community please see:
https://strokefoundation.org.au/What-we-do/Research/Request-for-research-participant-policy

12. Conditions of Research Grant Award

All Research Grants are offered in accordance with the conditions specified in the 'Stroke Foundation Clinical Trials Conditions of Research Grant Award' available on the Stroke Foundation website: https://strokefoundation.org.au/clinicaltrials

In signing an acceptance of the Clinical Trials Conditions of Research Grant Award, the grant Recipient is agreeing to abide by all the conditions, which includes but is not limited to;

- the research must be undertaken at the nominated institution/s;
- acknowledgement of the Australian Government's support and the Stroke Foundation in agreed format in any presentation or publication of the work;

- annual milestone and financial reporting, and a final report and financial acquittal provided at the end of the grant period;
- agreement that the grant Recipient may be contacted to represent the Stroke Foundation.

13. Varying a grant

Grant Recipients agree to perform the activities specified in the original application. If the Recipient is unable to perform, or to continue to perform, activities in relation to the award, the Stroke Foundation must be notified in writing as soon as practicable.

Variations occur when a grant needs modification from the original proposal submitted. This may include changes in budget or personnel or an amendment to the budget.

Extensions to a research project end date will only be considered in exceptional circumstances, with a maximum extension of 6 months. Requests to amend a grant or the terms and conditions should be made to research@strokefoundation.org.au and a Research Grant Variation Form will be provided.

14. Duration of grant and expenditure of funds

The 'Return to life, return to work' research grants are 2.5 year awards which take effect from the start of the award year (i.e. 1 January 2019 - 30 June 2021).

Funding will be released annually subject to the submission of annual milestone progress and financial reporting, and the Stroke Foundation Clinical Trials Conditions of Research Grant Award. Annual release of funding will be according to the Recipient's yearly budgets as submitted in the application, conditional to:

i. no more than s47(1)(b) budgeted per annum - PSE trial.
ii. s22 .

Annual financial acquittals prepared by the administering institution and in accordance with the yearly budgets submitted are required by 31 December each year of the grant award and at the conclusion of the grant (31 July 2021).

Expenditure of funds must be within the grant period and in accordance with the budget submitted, unless a variation has been approved by the Stroke Foundation. Funds that have not been spent at the conclusion of the award must be returned to the Stroke Foundation within 30 days of the invoice issued to the nominated institution.

15. Reporting

Annual milestone progress reports and financial acquittals are required (31 December each year), and a final report with financial acquittal at the conclusion of the grant (31 July 2021) must be submitted using the templates provided.

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Where a grant Recipient fails to submit satisfactory reports when required, the Stroke Foundation may determine that all or part of the funding must be repaid. In addition, a grant Recipient who fails to submit satisfactory reports may not be eligible to apply for future funding rounds of the Stroke Foundation Research Program. All information provided to the Stroke Foundation in progress and final reports may be used for internal reporting, media releases and in any Stroke Foundation publications.

16. Acceptance of grant

Successful applicants and their institutional contact will receive a Letter of Award by email to advise the offer of award. The successful applicant must return written acceptance of the offer of award and the specified documentation by the date nominated within the letter.

17. Review process

The Research Advisory Committee (RAC) oversees the Stroke Foundation Research Program. All applications will be reviewed and ranked by independent and external reviewers. Funding will be awarded to the highest ranking applications. Each funding scheme will be reviewed independently by reviewers allocated to the one scheme.

When reviewing the applications, reviewers are asked to score against each of the criteria outlined in the Descriptors (Descriptors available on the Stroke Foundation website: https://strokefoundation.org.au/clinicaltrials.

Each application is scored with a weighting of 50% for “Research Program” (scientific quality), and 25% for each of “Relevance" to each scheme and “Team Track Record”, by five independent reviewers. The reviewers each receive the same number of applications and, after scoring them, are asked to rank each application. Within each scheme, all of the ranks from all of the reviewers are then combined into one overall ranked list. The RAC is provided with a de-identified copy of these ranked lists. These lists provide a basis for funding recommendations.

18. Timeline of Peer Review Process

Stage	Date
Applications close	**5pm AEDT Friday 30 November 2018**
Applications assigned to external reviewers	December 2018
Grant Review Panel assess and rank applications	January 2019
Funding recommendations prepared	January 2019
RAC meet	February 2019
Advice to applicants	February 2019

Return to life, return to work Clinical Research Grants Application Guide

19. Enquiries

Any enquiries regarding the administration of grants should be addressed to:
Stroke Foundation: Compliance Officer, s47F
Email: research@strokefoundation.org.au
Telephone: 03 s47F

Acknowledgement

Funding for this research has been provided by the Medical Research Future Fund (MRFF). The MRFF has been established by the Australian Government to provide grants of financial assistance to support health and medical research and innovation, with the objective of improving the health and wellbeing of Australians. MRFF funding has been provided to Stroke Foundation under the MRFF Accelerated Research Program announced as part the MRFF's disbursement package in October 2018. Further information on the MRFF and disbursements are available at www.health.gov.au/mrff.

We would like to acknowledge Royal Melbourne Hospital Research Directorate for their assistance in providing materials and advice on these documents.

Return to life, return to work Clinical Research Grants Application Guide

FAQ's

International

Does the Stroke Foundation award grants internationally?
The research team must be Australian led, but internationally based Investigators and trial sites can be included in the proposal.

Is a project eligible if it is led by Australian researchers but collected data internationally?
Yes, the project could be considered if it also collected data for Australia or would benefit Australian patients.

Can a researcher from another country be the Chief Investigator for the grant, but the research be completed at an Australian University?
People from overseas can be a Chief Investigator, but a significant part of the research must be done in Australia and administered by an Australian institution. The contribution of international Investigators should be highlighted and the practicalities of conducting the study explained.

Grant funds

Are grants subject to the GST of the Stroke Foundation?
Yes.

Does the grant funding cover institutional fees/infrastructure costs/overheads/PhD stipends?
No, the grant funding does not cover any of the above costs.

Can grant funding be used for equipment, research assistant salaries, consumables and travel?
The funding can be for anything that contributes to the study objectives, but the costs must be justified.

Can severance pay be included in grant acquittals?
No. We only include costs that support the actual cost of the project, and so severance pay would not be included.

Clinical Trials Conditions of Research Grant Award

ATTACHMENT 3

1. General Terms

a. The research undertaken must conform to the principles set out by the NHMRC's Statement on Ethical Conduct in Human Research (2007) and The Australian Code for the Responsible Conduct of Research and any other conditions required by Human Research Ethics Committees. The research undertaken must align with Australasian Stroke Trials Network (ASTN) guidelines, and meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable[1].

b. The Recipient will obtain approval from relevant Ethics Committees and will provide copies of all approval forms to the Stroke Foundation Compliance Officer. The grant will be withdrawn if required approvals are not obtained by the final date by which the project must commence.

c. Requests for amendments to the terms of this award must be submitted to the Stroke Foundation Compliance Officer using the Grant Variation Form. Contact the Compliance Officer to access the Grant Variation Form.

d. The Recipient agrees to perform the activities specified in the original application. If the Recipient is unable to perform, or to continue to perform, activities in relation to the award, they must notify the Stroke Foundation Compliance Officer in writing immediately.

2. Acknowledgement

a. The research must be undertaken at the nominated institution/s and the Australian Government and the Stroke Foundation must be acknowledged in agreed format in any presentation or publication of the work.

b. Suitable acknowledgement should be made of the financial support awarded through the Medical Research Future Fund in the publication of reports or articles in any scientific journal or other publication. This must take the following form:

[1] Kwakkel G, et al. Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabil Neural Repair. 2017;31:793-799

Clinical Trials Conditions of Research Grant Award

"Funding for this research has been provided by the Medical Research Future Fund (MRFF). The MRFF has been established by the Australian Government to provide grants of financial assistance to support health and medical research and innovation, with the objective of improving the health and wellbeing of Australians. MRFF funding has been provided to Stroke Foundation under the MRFF Accelerated Research Program announced as part the MRFF's disbursement package in October 2018. Further information on the MRFF and disbursements are available at www.health.gov.au/mrff."

3. Finance

a. Funding will be released annually subject to the submission of annual milestone progress and financial reporting. Annual release of funding will be according to the Recipient's yearly budgets as submitted in the application. For the 'Return to life, return to work' grants this is conditional to:

   i. no more than s47(1)(b) budgeted per annum for the Perispinal Etanercept trial.
   ii. s22 .

b. Funding will be released following receipt of the required documentation as specified in the Letter of Award, which includes relevant evidence that Ethics Committee approval and ASTN endorsement has been obtained and submitted to the Stroke Foundation.

c. Expenditure of funds must be in accordance with either:

   i. the budget submitted in the original application; or

   ii. a variation to the original budget with prior approval by the Stroke Foundation. To vary your budget, please contact the Stroke Foundation Compliance Officer and submit a Grant Variation Form.

d. Funds that have not been spent at the conclusion of the award must be returned to the Stroke Foundation within 30 days of the invoice issued to the nominated institution.

4. Reporting

a. Annual milestone progress reports and financial acquittals are required at the end of each year (31 December), and a final report and financial acquittal at the conclusion of the grant (31 July 2021) submitted using the templates provided.

   NOTE: The Stroke Foundation may request further information and reporting on top of what is required in the Clinical Trials Conditions of Research Grant Award.

b. Where the Recipient fails to submit satisfactory reports as required, the Stroke Foundation may terminate funding and determine that all or part of the funding must be repaid.

c. All information provided to the Stroke Foundation in progress and final reports may be used for internal reporting, media releases and in any Stroke Foundation publications.

Clinical Trials Conditions of Research Grant Award

5. Notices

a. All correspondence relating to this grant must be directed to the Stroke Foundation Compliance Officer at research@strokefoundation.org.au

6. Terms of the Award

Application ID:

Recipient:

Institution:

Grant type:

Project title:

Reporting

Report	Frequency	Due
Milestone progress report	Annually	31 December each year
Financial acquittal	Annually	31 December each year
Final report and financial acquittal	Once only	At project completion (31 July 2021)
Ad hoc reports	As requested by Stroke Foundation	On request with negotiable timeframe not greater than 6 weeks

Acceptance of Offer

I (Chief Investigator), _____, accept this offer according to the terms and conditions of the award outlined in this document.
Signed: _____ Date: _____

I (Project Supervisor), _____, accept this offer according to the terms and conditions of the award outlined in this document.
Signed: _____ Date: _____

Perispinal Etanercept Clinical Trial Grant Application Form

ATTACHMENT 4

SUMMARY SHEET

Please read the Return to life, return to work Clinical Research Grants Application Guide and then complete this application form.

Name of Chief Investigator 'A' (Applicant)		
Applicant Email:		
Research Question:	**Does Perispinal Etanercept (PSE) promote recovery after chronic stroke in Australian stroke survivors of working age?**	☒
Research Project Title		
Funding requested: (Up to a maximum value of $750,000 exc GST over 2.5 years)	$	
Administering Organisation (Contact person must not be Applicant)	**Contact person:** **Name of institution:** **Postal address for contact person:** **Email of contact person:** **ABN of institution:**	

Perispinal Etanercept Clinical Trial Grant Application Form

Section 1: Project Summary

1.1. In half a page, outline the research question, methodology and significance of the project in trialling PSE as a therapy promoting recovery after chronic stroke in Australian stroke survivors of working age, and total amount of funds requested.

1.2. Has ethical approval for this project been obtained/applied for?

Yes ☐ No ☐

Please provide relevant details below

1.3 Consumer Engagement

Have you involved a consumer in your study design? If so, provide details of how this has occurred.

Yes ☐ No ☐

1.4. Research Team

The research team must be Australian led but international trial sites may be included in the project. List up to ten (10) Chief Investigators in the research team. (Delete unused lines below where applicable.)

Role	[Title] [First name] [Surname]	[Department], [School], [Organisation]
Chief Investigator A (Applicant)		
Chief Investigator B		
Chief Investigator C		
Chief Investigator D		
Chief Investigator E		
Chief Investigator F		
Chief Investigator G		
Chief Investigator H		
Chief Investigator I		
Chief Investigator J		

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Perispinal Etanercept Clinical Trial Grant Application Form

Section 2: Research Proposal

Responses to 2.1. to 2.5. can be no longer than 9 pages in length and must adhere to the formatting requirements stated in the Application Guide (Section 7).

2.1 Background and Rationale:

2.2 Research aims and Hypotheses:

2.3 Detailed research plan (including randomisation process, inclusion criteria, exclusions, baseline and outcome assessments, etc.):

2.4 Sample Size Justification and Statistical Analysis:

2.5 Project outcomes (clearly defined) and Significance:

2.6 Timeline and Milestones: Outline up to **10 milestones**, with space allowable as required for a heading and two sentence description. **Mandatory milestones** for this grant are included below. Ensure these are incorporated within the 10 milestones. (**Milestone progress reports required annually.**)

1. ASTN Endorsement – by June 2019
Endorsement of the trial by the Australasian Stroke Trials Network, ethics and governance approval and trial registration (Sites participating will be identified)

2. Establish an independent Data Safety and Monitoring Committee - by June 2019.
Finalise the Committee's Charter. The Committee will meet when required to review the study data.

3. Training of staff at trial sites – by December 2019
Staff at each identified site will be trained in undertaking the trial, including separate training for those administering the study and for those undertaking blinded outcome assessments. All staff will obtain certification for Good Clinical Practice (GCP).

4. Publication of study protocol and statistical analysis plan – by December 2020.
The detailed study protocol will be published in an international scientific journal. The statistical analysis plan will be devised and published in an international journal prior to unblinding the group allocation.

Perispinal Etanercept Clinical Trial Grant Application Form

5. Patient recruitment concludes with recruitment targets achieved - by December 2020.

6. Clinical Trial close out – by 30 June 2021.
Closure of sites, patient follow-up finalised, results written up and presented, publication plan. The results will be analysed according to the pre-defined statistical analysis plan, and papers will be published.

Perispinal Etanercept Clinical Trial Grant Application Form

Section 3: Research Team

3.1. CI Track Record including the Top 5 publications in the last 5 years

Provide a track record summary for each Chief Investigator that is relevant to this application and relative to opportunity and career stage. If applicable, note any career disruptions that may be relevant to career history. Include the top 5 publications in the last 5 years relevant to this application. For each Chief Investigator, up to 2 pages in length is allowable. (Delete unused boxes where applicable.)

Chief Investigator A: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator B: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator C: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator D: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator E: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator F: CI Track Record and Top 5 publications(up to 2 pages in length)

Chief Investigator G: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator H: CI Track Record and Top 5 publications (up to 2 pages in length)

Chief Investigator I: CI Track Record and Top 5 publications (up to 2 pages in length)

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Chief Investigator J: CI Track Record and Top 5 publications (up to 2 pages in length)

3.2. Publication Track Record for Chief Investigators

A full list of publications **since 2014 for each Chief Investigator only** may be attached as a separate document. **Note:** Group publications by type (original articles, reviews, editorials, letters to the editor, book chapters, books). **Exclude** published abstracts from this list.

3.3. Describe how the team will work together to achieve the project aims, and the overall team quality and capability (up to 1 page in length is allowable)

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Perispinal Etanercept Clinical Trial Grant Application Form

Section 4: Project Budget & Justification of Budget

Enter details of the proposed research budget with justification for each component below, including:

- The item type (e.g. Personnel, equipment, travel related to data collection, consumables)
- The name/description of the item
- The total value of the item requested for each year
- A justification for the particular item requested. This must align with the proposed aims of the study, be detailed on a yearly basis, and be fully justified.

Please note:

- A maximum of s47(1)(b) over 2.5 years can be requested for this Grant.
- Funding will be released annually and according to yearly budgets, conditional to no more than s47(1)(b) budgeted in any one year.
- Financial acquittals are required annually in line with yearly project budgets.
- Funding cannot be used for infrastructure/institutional fees/overheads/Phd stipends.

4.1. Project Budget - Items requested	**Amount requested (ex GST)**		
Please add a new line for each item requested.	**2019**	**2020**	**2021**
	2019 Total:	**2020 Total:**	**2021 Total:**

2019-2021 Project Budget Total:	

Perispinal Etanercept Clinical Trial Grant Application Form

4.2. Justification of each budget item *Personnel:* *Direct Research Costs:* *Equipment:*

Perispinal Etanercept Clinical Trial Grant Application Form

Section 5: References

Provide a full list of references cited in this document (space allowable as required).

References:

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Perispinal Etanercept Clinical Trial Grant Application Form

Section 6: Certifications

Certification by Chief Investigator A (Applicant)

☐ I certify that to the best of my knowledge the details provided in this application form and in any supporting documentation are true and complete.

☐ I certify that I meet all the eligibility criteria for a Chief Investigator as outlined in the Return to life, return to work Clinical Research Grants Application Guide.

Name of Applicant (please print)	Signature of Applicant	Date

Certification by the Head of Department in the administering institution/research body

☐ I certify that:

- I am prepared to have the project carried out in my institution under the circumstances set out by the applicant/s;
- To the best of my knowledge all details on this application form are true and complete;
- The amount of time which the investigator/s will be devoting to the project is appropriate to existing workloads;
- This institution supports this application and if successful it will provide basic infrastructure for the project;
- The project can be accommodated within the general facilities in this institution and that sufficient working and office space is available for any proposed additional staff.

Name of Head of Department (please print)	Signature of Head of Department	Date

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ATTACHMENT 6

Peer Review 2018: Perispinal Etanercept (PSE) Clinical Trial Grant Application
7-Category Descriptor Scale

One (1) grant of up to s47(1)(b) over 2.5 years available to support a clinical trial that addresses:
"Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age)."

Category	7	6	5	4	3	2	1
Category Descriptor	**Highest International Quality and Research Performance**	**Excellent**	**Highly Competitive**	**Good**	**Satisfactory***	**Marginal***	**Poor***
Notes	*It is anticipated that only 1-5% of applications will fall into this category.*	*The panel regards these applications as in the "absolutely must fund" category. It is anticipated that 5-10% of applications will fall into this category with a maximum of 10% in categories 6 & 7.*	*The panel regards these applications as in the "strong desire to fund" category. It is anticipated that approximately 15% of applications will fall into this category.*	*The panel regards these applications as in the "fundable" category, budgetary restrictions aside. It is anticipated that approximately 25% of applications will fall into this category.*	**It is anticipated that approximately 50% of applications will fall into categories 1, 2 or 3.*		
Criteria:							
Relevance	The planned work will result in a **highly significant** advance in knowledge which addresses an issue of **great importance** to stroke and ***will*** translate into fundamental outcomes in the science and practice of clinical medicine, public health, or in health policy. The planned research: • **directly targets** the **research question** listed above • will ***almost certainly*** result in **highly influential** publications • will ***almost certainly*** be the subject of invited plenary presentations at national and international meetings, often with relevance across several fields. • is highly innovative and introduces advances in concept(s) • will use very advanced approaches which will optimize outcomes	The planned work will result in a **significant** advance in knowledge which addresses an issue of importance to stroke and **is likely** to translate into fundamental outcomes in the science and practice of clinical medicine, public health, or in health policy. The planned research: • ***directly addresses*** the **research question** listed above • will **likely** result in **influential** publications • will **likely** be the subject of invited plenary presentations at international and national meetings. • is **highly** innovative in concept • will use **advanced** approaches to enhance outcomes.	The planned work will **advance** knowledge in this field which addresses an issue of importance to stroke and **may translate** into fundamental outcomes in the practice of clinical medicine, public health or in health policy. The planned research • ***addresses*** the **research question** listed above • is likely to result in some **very strong** publications • **could** be the subject of invited plenary presentations at international and national meetings • **is** innovative in concept • Will use **well established** approaches to good effect	The planned work may **incrementally** advance knowledge which addresses an issue of some importance to stroke, but is **unlikely to translate** into fundamental outcomes in the practice of clinical medicine, public health or in health policy. The planned research • although it ***addresses*** the **research question** listed above, this is only 40-60% of the focus of the application • may result in some **good but not excellent** publications • Is **unlikely to** be the subject of invited plenary sessions at international meetings • less solid in concept • Will in the main use **standard** approaches	Category 3 includes applications which, budgetary restrictions aside, are fundable, based on a satisfactory research approach and design. There is no question that the applicant(s) will be able to undertake the research. However, on balance the application is one that is not competitive in the Stroke Foundation round this year.	These applications display a number of good features but are not competitive.	Unfundable grants (reasons must be clearly articulated to applicants).
Research Program	The **proposal has a research plan that**: • is **well-defined**, highly coherent and strongly developed. • has a **near flawless** study design. • is **highly feasible** with all of the required expertise, research tools and techniques established. • would be highly competitive with the best, similar research proposals internationally.	The **proposal has a research plan that**: • is clearly **defined**, coherent and well developed. • has a strong study design. • is **feasible** with all required tools, techniques and expertise established. • is likely to be competitive with strong, similar research proposals internationally.	The **proposal has a research plan that**: • is **generally clear** in its scientific plan and is logical. • raises only a few **minor concerns** with respect to the study design. • is **feasible in all, or almost all areas** - required techniques and tools either established or nearly established. • may not be highly competitive with similar research proposals internationally.	The **proposal has a research plan that**: • is **generally solid** in its scientific plan, but may not always be clear in its in its intent and may lack some focus. • raises **several concerns** regarding the study design. • raises **doubts** about the feasibility in some areas. • is not likely to be competitive with similar research proposals internationally.			
Team Track Record	**Relative to opportunity**, the applicant(s): • has expertise that **specifically targets the proposed research** both in terms of its depth and/or breadth. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice that is **outstanding by international standards** commensurate with their field of research. • if junior members are involved they are supported by **outstanding** senior members who will provide a **very strong** mentoring environment.	Relative to opportunity, the applicant(s): • has expertise that is **highly relevant** to the proposed research both in terms of its depth and/or breadth. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice that is **excellent by international standards** commensurate with their field of research. • if junior members are involved they are supported by **excellent** senior members who will provide a **strong** mentoring environment.	Relative to opportunity, the applicant(s): • has expertise that is relevant to the proposed research, and there are only **minor concerns** regarding the depth and/or breadth of expertise. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice which places it **well above average** for their peers or cohort. • if junior members are involved they are supported by members with **very good and growing** reputations who may provide some mentoring	Relative to opportunity, the applicant(s): • has expertise that is relevant to the proposed research, but there are **some significant concerns** regarding the depth and/or breadth of expertise. • has, over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice, that places them at an **average** level for their peers/cohort. • if junior members are involved they are supported by members with **good and growing** reputations, but there is little or no evidence of a mentoring framework to support them			

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ATTACHMENT 7

Peer Review 2018: Return to Work Clinical Trial Grant Application
7-Category Descriptor Scale

One (1) grant of up to s47(1)(b) over 2.5 years to support a clinical trial that addresses:
"Returning to work for younger stroke survivors in Australia."

Category	7	6	5	4	3	2	1
Category Descriptor	**Highest International Quality and Research Performance**	**Excellent**	**Highly Competitive**	**Good**	**Satisfactory***	**Marginal***	**Poor***
Notes	*It is anticipated that only 1-5% of applications will fall into this category.*	*The panel regards these applications as in the "absolutely must fund" category. It is anticipated that 5-10% of applications will fall into this category with a maximum of 10% in categories 6 & 7.*	*The panel regards these applications as in the "strong desire to fund" category. It is anticipated that approximately 15% of applications will fall into this category.*	*The panel regards these applications as in the "fundable" category, budgetary restrictions aside. It is anticipated that approximately 25% of applications will fall into this category.*	**It is anticipated that approximately 50% of applications will fall into categories 1, 2 or 3.*		
Criteria:							
Relevance	The planned work will result in a **highly significant** advance in knowledge which addresses an issue of **great importance** to stroke and ***will*** translate into fundamental outcomes in the science and practice of clinical medicine, public health, or in health policy. The planned research: • **directly targets** the **research question** listed above • will ***almost certainly*** result in **highly influential** publications • will ***almost certainly*** be the subject of invited plenary presentations at national and international meetings, often with relevance across several fields. • is highly innovative and introduces advances in concept(s) • will use very advanced approaches which will optimize outcomes	The planned work will result in a **significant** advance in knowledge which addresses an issue of importance to stroke and **is likely** to translate into fundamental outcomes in the science and practice of clinical medicine, public health, or in health policy. The planned research: • ***directly addresses*** the **research question** listed above • will **likely** result in **influential** publications • will **likely** be the subject of invited plenary presentations at international and national meetings. • is **highly** innovative in concept • will use **advanced** approaches to enhance outcomes.	The planned work will **advance** knowledge in this field which addresses an issue of importance to stroke and **may translate** into fundamental outcomes in the practice of clinical medicine, public health or in health policy. The planned research • ***addresses*** the **research question** listed above • is likely to result in some **very strong** publications • **could** be the subject of invited plenary presentations at international and national meetings • **is** innovative in concept • Will use **well established** approaches to good effect	The planned work may **incrementally** advance knowledge which addresses an issue of some importance to stroke, but is **unlikely to translate** into fundamental outcomes in the practice of clinical medicine, public health or in health policy. The planned research • although it ***addresses*** the **research question** listed above, this is only 40-60% of the focus of the application • may result in some **good but not excellent** publications • Is **unlikely to** be the subject of invited plenary sessions at international meetings • less solid in concept • Will in the main use **standard** approaches	Category 3 includes applications which, budgetary restrictions aside, are fundable, based on a satisfactory research approach and design. There is no question that the applicant(s) will be able to undertake the research. However, on balance the application is one that is not competitive in the Stroke Foundation round this year.	These applications display a number of good features but are not competitive.	Unfundable grants (reasons must be clearly articulated to applicants).
Research Program	The **proposal has a research plan that**: • is **well-defined**, highly coherent and strongly developed. • has a **near flawless** study design. • is **highly feasible** with all of the required expertise, research tools and techniques established. • would be highly competitive with the best, similar research proposals internationally.	The **proposal has a research plan that**: • is clearly **defined**, coherent and well developed. • has a strong study design. • is **feasible** with all required tools, techniques and expertise established. • is likely to be competitive with strong, similar research proposals internationally.	The **proposal has a research plan that**: • is **generally clear** in its scientific plan and is logical. • raises only a few **minor concerns** with respect to the study design. • is **feasible in all, or almost all areas** - required techniques and tools either established or nearly established. • may not be highly competitive with similar research proposals internationally.	The **proposal has a research plan that**: • is **generally solid** in its scientific plan, but may not always be clear in its in its intent and may lack some focus. • raises **several concerns** regarding the study design. • raises **doubts** about the feasibility in some areas. • is not likely to be competitive with similar research proposals internationally.			
Team Track Record	**Relative to opportunity**, the applicant(s): • has expertise that **specifically targets the proposed research** both in terms of its depth and/or breadth. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice that is **outstanding by international standards** commensurate with their field of research. • if junior members are involved they are supported by **outstanding** senior members who will provide a **very strong** mentoring environment.	Relative to opportunity, the applicant(s): • has expertise that is **highly relevant** to the proposed research both in terms of its depth and/or breadth. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice that is **excellent by international standards** commensurate with their field of research. • if junior members are involved they are supported by **excellent** senior members who will provide a **strong** mentoring environment.	Relative to opportunity, the applicant(s): • has expertise that is relevant to the proposed research, and there are only **minor concerns** regarding the depth and/or breadth of expertise. • has over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice which places it **well above average** for their peers or cohort. • if junior members are involved they are supported by members with **very good and growing** reputations who may provide some mentoring	Relative to opportunity, the applicant(s): • has expertise that is relevant to the proposed research, but there are **some significant concerns** regarding the depth and/or breadth of expertise. • has, over the last 5 years, a combined record of research achievement quality and productivity and/or translation into practice, that places them at an **average** level for their peers/cohort. • if junior members are involved they are supported by members with **good and growing** reputations, but there is little or no evidence of a mentoring framework to support them			

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Media release

Saturday October 6, 2018

Recovery research boost

Stroke Foundation has welcomed the Federal Government's $1 million dollar research boost to support new, innovative and cutting edge treatment options to aid stroke recovery.

The *Return to Life, Return to Work* research package has the potential to provide new medicines to working-age Australians impacted by stroke.

Stroke Foundation Chief Executive Officer Sharon McGowan applauded the Federal Government for investing 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," Ms McGowan 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 fulfill them most," she said.

The *Return to Life, Return to Work* research package has been funded by the Federal Government through the Medical Research Future Fund. Funding will be provided over three years. The research package includes Australia's first multicentered clinical trial of Perispinal Entanercept in chronic stroke.

This funding builds on the $1.5 million announced by Minister for Health the Hon Greg Hunt in August to allow the Stroke Foundation and Cochrane Australia to provide health professionals with the latest clinical guidelines and real-time research findings, to give stroke patients the best chance for survival.

Stroke Facts

- One stroke every nine minutes in Australia.
- Estimated 142,500 (30 percent of 475,000) Australian stroke survivors of working age.
- 20 strokes a day impacting Australians of working-age.
- International evidence indicates stroke among younger people is on the increase in large part due to lifestyle factors.
- More than $972 million in lost earnings caused by reduced unemployment due to stroke in working age Australians.

Media Contact: s47F **p)** s47F
e) media@strokefoundation.com.au **Website:** www.strokefoundation.com.au

ATTACHMENT 9

Stroke Foundation Research Program

Applications now open 'Return to life, return to work' clinical research grants for 2019

Supported by the Australian Government's Medical Research Future Fund (MRFF), the Stroke Foundation is facilitating a targeted clinical research investment in recovery for working age survivors of chronic stroke through two dedicated research grants funded from 2019-2021:

1. **Clinical Trial: Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age).**
2. **Clinical Trial: Return to work (RTW) for younger stroke survivors in Australia.**

The **'Return to life, return to work'** initiative will fund projects aimed at developing innovative recovery and rehabilitation clinical interventions for younger stroke survivors in Australia - an emerging priority area with unmet needs. These projects will continue to accelerate important neurological research and support Australian researchers to be at the forefront of finding solutions for stroke recovery.

Critical dates:

Applications open: 8 October 2018

Applications close: 5pm AEDT Friday 30 November 2018

Advice to applicants: February 2019

To Apply

For information on how to apply and more on the grants **click here**.

Applications will be assessed by peer review and in accordance with the criteria outlined in the relevant Descriptor.

- **Perispinal Etanercept Grant 7 Point descriptor scale 2018**
- **Return to Work Grant 7 Point descriptor scale 2018**

For any enquiries and to submit your application please contact research@strokefoundation.org.au or phone 03 9918 7215

Acknowledgement

Funding for this research has been provided by the Medical Research Future Fund (MRFF). The MRFF has been established by the Australian Government to provide grants of financial assistance to support health and medical research and innovation, with the objective of improving the health and wellbeing of Australians. MRFF funding has been provided to Stroke Foundation under the MRFF Accelerated Research Program announced as part the MRFF's disbursement package in October 2018. Further information on the MRFF and disbursements are available at **www.health.gov.au/mrff**.

GV006 PO: Conflict of Interest

ATTACHMENT 10

Purpose

The purpose of this policy and associated procedures is to ensure that in dealings with internal and external persons, entities and/or organisations, Stroke Foundation People observe the highest standards of business ethics and avoid any activity or interest that might reflect unfavourably on that individual's integrity and/or good name or on the integrity and/or good name of the National Stroke Foundation (Stroke Foundation).

Scope

This policy applies to Stroke Foundation People and Related Parties as defined below.

Definitions

Term	Definition
Stroke Foundation People	For the purpose of this policy, the term 'Stroke Foundation People' or 'Stroke Foundation Person' refers to any person or group of people who act for or on behalf of Stroke Foundation including: › Board Members › Board Sub-Committee Members which include: Research Advisory Committee; Audit, Finance Investment and Risk Committee; Governance and Nominations Committee; Clinical Council; Consumer Council › External Research Grant Assessors › Workforce Members (employees and volunteers) › Individuals who represent the Stroke Foundation in any manner

GV006 PO: Conflict of Interest

Stroke Foundation Executive	The Chief Executive Officer (CEO), Chief Financial Officer (CFO) and Executive Directors
Conflict of Interest	A conflict of interest occurs when a Stroke Foundation Person's personal, institutional or business interests conflicts with their responsibility to act in the best interests of the Stroke Foundation. If a particular decision is likely to benefit a Stroke Foundation Person in any way, or benefit a Related Party, that Stroke Foundation Person is considered to be no longer in a position to make an impartial decision and is therefore considered to have a Conflict of Interest (COI). It also includes a conflict between a board member's duty to Stroke Foundation and another duty that the board member has (for example, to another board). A conflict of interest may be actual, potential or perceived, and may be financial or non-financial.
Related Party	A Related Party is a person or entity that is related to Stroke Foundation. A person or a close member of a Stroke Foundation Person's family is related to the Stroke Foundation if that Stroke Foundation Person: i. has control or joint control over the Stroke Foundation; ii. has significant influence over the Stroke Foundation; or iii. is a member of Key Management Personnel of Stroke Foundation as defined within the Australian Accounting Standards Board AASB 124. Stroke Foundation relies on the conditions within AASB 124 to define a Related Party entity.
Related Party Transaction	A Related Party Transaction is a transfer of resources, services, or obligations between Stroke Foundation and a Related Party, regardless of whether a price is charged.

GV006 PO: Conflict of Interest

Responsibilities

The board is responsible for:

1. establishing a system for identifying, disclosing and managing conflicts of interest across the charity
2. monitoring compliance with this policy, and
3. reviewing this policy on an annual basis to ensure that the policy is operating effectively.

Board members must be aware of the ACNC governance standards, particularly governance standard 5, and that they disclose any actual or perceived material conflicts of interests as required by governance standard 5 and in accordance with this policy.

Policy

1. The key principles underpinning the treatment of identified **COI** and/or **Related Party Transactions** are that they must be:
   a. declared, documented and submitted to the CFO,
   b. a management plan determined, submitted to and approved by the CFO, and
   c. where beneficial or required by accounting standards, publically disclosed.
2. The Stroke Foundation accepts that situations arise from time to time where, for various reasons, some Stroke Foundation People may have a reasonably **perceived, potential or actual COI**. For clarity, the following guidelines apply:
   a. Stroke Foundation People must not be involved in clinical advice or representation when:
      i. They are in paid employment, including paid consultancy, or receive speaker fees or advisory fees from a pharmaceutical company active in Cardiovascular Disease (CVD) Risk Management to the value of >AUD$10,000 per year; or
      ii. They have shareholdings in a pharmaceutical company active in the area of CVD Risk Management.
   b. Stroke Foundation People must not:
      i. Conduct business on behalf of the Stroke Foundation with a Related Party;
      ii. Divert Stroke Foundation business away from another supplier, customer, or other person or entity to a Related Party;

GV006 PO: Conflict of Interest

iii. Be involved in a human resource or assessment matter such as recruitment and selection, promotion, disciplinary procedures, workforce development, or performance review and remuneration of a Related Party;

c. Stroke Foundation People must not seek or accept for themselves or on behalf of anyone else from any organisation, person, or entity which does or seeks to do business with the Stroke Foundation, any gift, entertainment benefit, travel benefit, accommodation benefit, or other favours of a character which go beyond common courtesies consistent with ethical and accepted business practices.

d. Stroke Foundation People found to have a significant COI will not be involved in the review of research grant applications. Potential COI will be assessed by the Research Advisory Committee Chair in accordance with guidelines taken from the NHMRC's National Statement on Ethical Conduct in Human Resources:

i. In the case of collaborations and relationships (e.g. publications, grants, etc.), did these activities occur five or more years ago, or are they more recent?

ii. What is/was the extent of the collaborations (e.g. frequent direct interaction or only familiarity with an individual through a common institution)?

iii. Is the collaboration (e.g. through publications, grants, etc.), with a Chief Investigator, or an Associate Investigator?

e. Research Advisory Committee Members will not be involved in decisions about the ranking of applications in which they have declared a COI.

3. At the time of appointment and on an annual basis thereafter, members of the Stroke Foundation Board, Sub-Committees, Executive and Leadership Teams must declare any private interests including, but not limited to:

- Office holdings
- Shareholdings and other business interests in suppliers, customers, competitors etc.
- Agreements
- Other substantial financial or other interest held.

4. Other Stroke Foundation People may be required to formally declare their private interests annually or ad hoc if they or their role is assessed by the CFO as warranting such on the basis of potential, perceived or actual COI risk.

5. Stroke Foundation People who believe they may have a conflict of interest must discuss the potential conflict with the Chair of the relevant Board, Sub-Committee

or Research Advisory Committee (in the case of Board, Sub-Committee or Research Advisory Members) or with their direct line manager (in the case of Stroke Foundation Employees and Volunteers).

6. Stroke Foundation People who are unclear who to raise the potential conflict of interest with must consult with the CFO who will advise the appropriate course of action.

Compliance with this policy

If the board has a reason to believe that a Stroke Foundation person subject to the policy has failed to comply with it, it will investigate the circumstances.

If it is found that this person has failed to disclose a conflict of interest, the board may take action against them. This may include disciplinary action for employees and volunteers and removal or expulsion of board members in accordance with clause 7.4 and 13.9 of the Stroke Foundation Company Constitution.

If a Stroke Foundation person suspects that a board member or other Stroke Person has failed to disclose a conflict of interest, they must discuss with the person in question and/or notify their manager, CFO or CEO or President of the Board.

Policy owner

The Executive is responsible for reviewing this policy every two years.

Policy approver

The Stroke Foundation Board is responsible for approving this policy every two years.

Supporting Documentation

Forms and Records Management	Location
Conflict of Interest Procedures	Conflict of Interest Procedures 201702 v2.docx
Declaration of Private Interests	O:\Your NSF\5.Policies & Procedures\Conflict of Interest - Declaration of Private Interests Form FINAL.pdf
Conflict of Interest Disclosure Form	O:\Your NSF\5.Policies & Procedures\Conflict of Interest - Disclosure Form 2017.pdf

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Australian Accounting Standards Board AASB 124	http://www.aasb.gov.au/Pronouncements/Current-standards.aspx
Guideline for Managing Conflicts of Interest in NHMRC Peer Review	https://www.nhmrc.gov.au/book/chapter-5-4-conflicts-interest
ACNC MANAGING CONFLICTS OF INTEREST - A guide for charity board members	http://www.acnc.gov.au/ACNC/Publications/COIguide/COIGuide1.aspx

Version History

Version	Date of change	Approval date	Approved by	Summary of change
4.0	February 2018	1 March 2018	Board	Corrected definition of Conflict of Interest. Responsibilities section and Compliance section added
3.0	September 2017	5 October 2017	Board	Added point to include all staff and volunteers may be required to declare interests annually or ad hoc. Included conflict of interest related to research grants review. Separation of policy and procedure. Editorial amendments to reflect organisational change.
2.0	October 2014	14 October 2014	Board	Amended to incorporate Related Party Transaction disclosure requirements
1.0	August 2013	4 August 2013	Board	New Policy and Procedure

Next review date: March 2020

International Review Panel - PSE applications

ATTACHMENT 11

S47F

International Review Panel - PSE applications

S47F

International Review Panel - PSE applications

S47F

Return to life, return to work

Stroke Medical Research Future Fund Package

1. Contents

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)[1] Australian stroke survivors are of working age. International evidence shows incidence of stroke among young people is increasing[2].
- 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.

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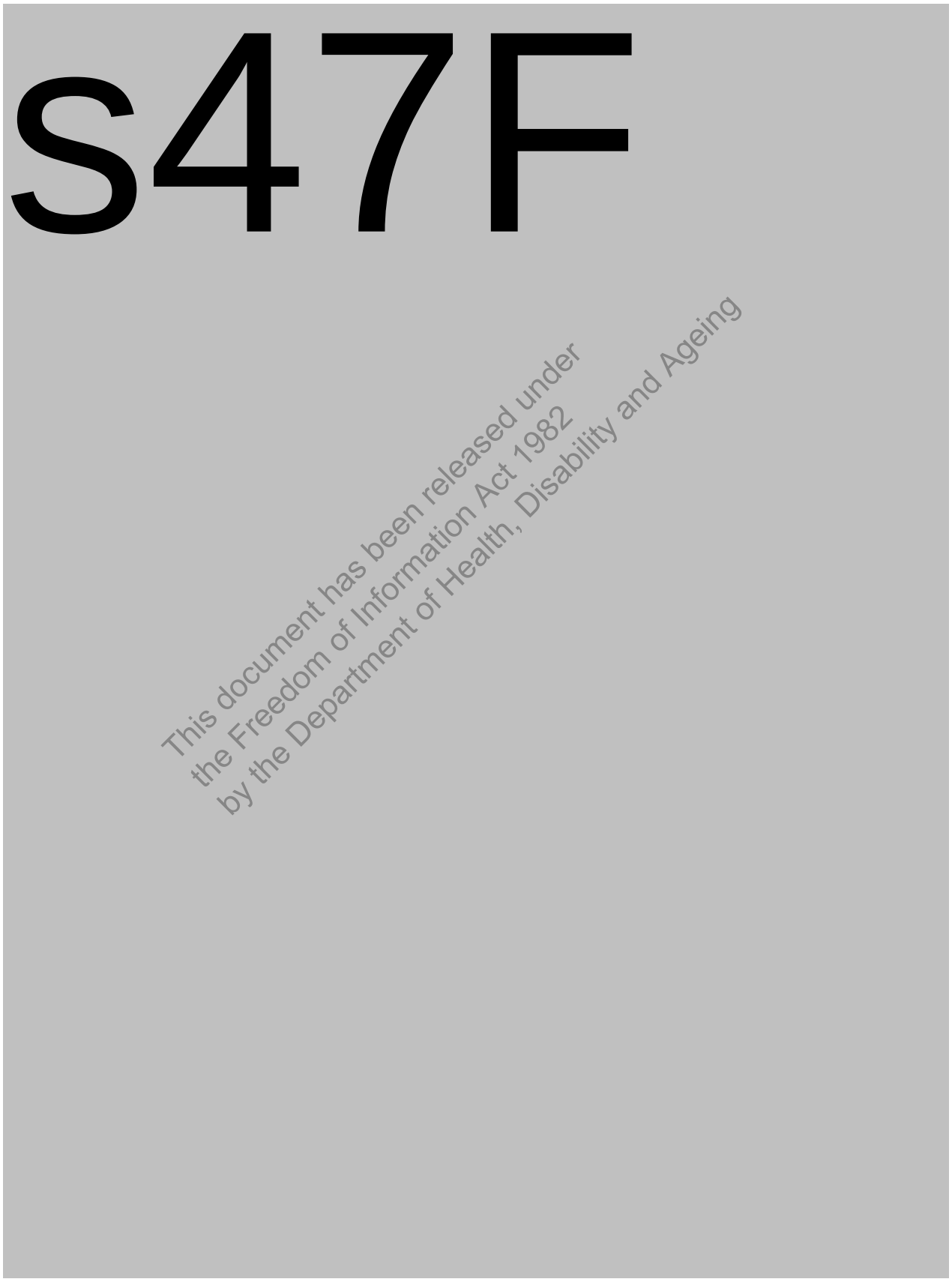
[1] Deloitte Access Economics – Impact of stroke across Australia. 2014

[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.

The human face of stroke



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)[1] 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.[2] 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.[3] 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.[4] 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.[4]

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.[5]

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.[6] In addition, there is a lack of high quality evidence on the effectiveness of vocational rehabilitation interventions in returning stroke survivors to work.[7] 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.

5. 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.
6. https://informme.org.au/en/Guidelines/Clinical-Guidelines-for-Stroke-Management-2017
7. 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.[8]

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 than 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[9] 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.

[8] www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data

[9] 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	■											
Commencement												
Mid way report				■	■							
Manage												
Manage process, stakeholders and budget; report	■	■	■	■	■	■	■	■	■	■	■	■
Evaluate												
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

Alignment with Australian Government Medical Research Future Fund Priorities

Strategy 2016 – 2021

VISION: A health system fully informed by quality health and medical research.

Identifies key strategic investment platforms set to position Australia to meet future health challenge:

- Strategic and international horizons.
- Data and Infrastructure.
- Health services and systems research.
- Capacity and collaboration.
- Trials and translation.
- Commercialisation.

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:
s47F
National Manager Public Affairs and Advocacy
Stroke Foundation
Level 7, 461 Bourke St, Melbourne VIC 3000
D +s47F
StrokeLine: 1800 STROKE (1800 787 653)
s47F @strokefoundation.org.au

Australian Government
Department of Industry, Innovation and Science

Business

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Application Form

Medical Research Future Fund - Accelerated Research - neurological (National Stroke Foundation)

Version April 2018

You should use this form to provide details about your proposal. We will enter these details in our online portal, which you will use for future transactions regarding your grant. You will need to register

Sometimes we may refer to your proposal as an application in this document, other documents including the grant agreement, or in the online portal. The terms proposal and application are interchangeable.

Instructions

About the Accelerated Research program

The Accelerated Research program (the program) was announced as part of the Medical Research Future 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

About the Accelerated Research - neurological (National Stroke Foundation Inc)] research grant opportunity

This grant opportunity was announced as part of the Accelerated Research program.

The objectives of the grant opportunity are:

- To support neurological research

Completing this form

You should read the Accelerated Research –neurological (National Stroke Foundation Inc) grant opportunity guidelines (guidelines) before filling out this application form.

This application form contains the following:

- Part A – Eligibility
- Part B – Contact details
- Part C – Applicant information
- Part D – Project details and funding
- Part E – Merit criteria
- Part F – Supporting documentation
- Part G – Applicant declaration

Disclosure of personal and confidential information

For information regarding the Department of Industry, Innovation and Science's (the department's) obligations in accordance with the Privacy Act, refer to the department's Privacy Policy[1].

Getting help

If you require assistance completing this application form you can contact us at arp@industry.gov.au .

You should also ensure you have read the guidelines and sample grant agreement before seeking help.

1 https://industry.gov.au/Pages/PrivacyPolicy.aspx

Submitting your proposal

You may submit your proposal at any time up until 5.00pm AEST on 31 May 2018.

A. Eligibility

A.1. Eligible entities

This section will help you determine whether you are an entity eligible for the grant opportunity.

You are required to answer all questions in this section.

Is your organisation an entity incorporated in Australia?	☒ yes	☐ no
Is your organisation an incorporated trustee applying on behalf of a trust? *You must be able to provide trust documents showing the relationship of the incorporated trustee to the trust.*	☐ yes	☒ no

If you have answered '**yes**' to either of the questions above you are eligible to apply for this grant opportunity.

A.2. Additional eligibility criteria

This section will help you determine whether you comply with additional eligibility criteria for the grant opportunity.

You are required to answer all questions in this section.

Is your organisation a legal entity able to enter into a legally binding agreement?	☒ yes	☐ no
Has your organisation been invited to apply? *You must have received an invitation in writing to apply for this grant opportunity*	☒ yes	☐ no
Does your organisation have an ABN? *For trustees applying on behalf of a trust, this refers to the ABN of the trust.*	☒ yes	☐ no

If you answered '**yes**' to all of the questions above you are eligible to apply for this grant opportunity.

For further information regarding eligibility requirements refer to the grant opportunity guidelines.

A.3. Select your area of research

Neurological

B. Contact details

B.1. Details of primary contact

Person authorised to act on behalf of the applicant.

The fields below are mandatory except for title.

Provide details of the primary contact.

Title	s47F
Given name	
Family name	
Position title	Chief Executive Officer
Phone number	03 s47F
Mobile number	s47F
Email address	s47F @strokefoundation.org.au

Provide the postal address of the primary contact

Address	Level 7, 461 Bourke Street
Suburb/ town	Melbourne
State/ territory	Victoria
Postcode	3000
Country	Australia

B.2. Contact's relationship to applicant

Is the applicant the primary contact's employer? ☒ yes ☐ no

If you answered '**yes**' go the next question. If you answered '**no**' complete the following table.

What is the relationship of the primary contact to the applicant?	
Name of primary contact's employer	
Australian Business Number (ABN) of primary contact's employer	

Provide a contact for the applicant organisation

Title
Given name
Family name
Position title
Phone number
Mobile number
Email address

C. Applicant information

C.1. Type of applicant

In this section you must indicate your entity type.

Select your entity type

☒	Australian public company
☐	Other incorporated entity
☐	Incorporated trustee on behalf of a trust

C.2. Applicant details

If you are applying as a trustee on behalf of a trust leave this question blank and go to the next question.

Australian Business Number (ABN)	42 006 173 379
Australian Company Number (ACN) *If applicable*	
Entity name *The entity name refers to the legal/ registered name that appears on official business documents. The entity name may be different from the business name.*	National Stroke Foundation
Business/ trading name *Your organisation may have one or more registered business names. Provide any relevant business or trading names here.*	Stroke Foundation
GST registered?	☒ yes ☐ no

C.3. Trustee and trust details

Australian Business Number (ABN) of the trustee *(if different to trust, otherwise leave blank)*
Australian Company Number (ACN) of the trustee
Entity name of the trustee *The entity name refers to the legal/ registered name that appears on official business documents. The entity name may be different from the business name.*

Australian Business Number (ABN) of the trust	
Entity name of the trust	
Business/ trading name *Your organisation may have one or more registered business names. Provide any relevant business or trading names here.*	
Is the trust GST registered?	☐ yes ☐ no

You must provide trust documents showing the relationship of the [incorporated] trustee to the trust.

C.4. ANZSIC details

What is your organisation's main revenue earning activity under the Australian and New Zealand Standard Industrial Classification (ANZSIC)? *The ANZSIC codes and titles are available from the Australian Bureau of Statistics (ABS) website. Phone 13 28 46 if you require assistance.*	Q8790

C.5. Address details

Provide your **organisation's street address** (Australian head office).

Address	Level 7, 461 Bourke Street
Suburb/ town	Melbourne
State/ territory	Victoria
Postcode	3000

Provide your **organisation's postal address**.

☒ Same as your street address, go to next section.

☐ Different to your street address, provide details below.

Address	
Suburb/ town	
State/ territory	
Postcode	
Country	Australia

C.6. Website address

Provide your organisation's website address.

www.strokefoundation.org.au

C.7. Project site address

Will your project's activities occur solely at the above listed head office address?	☐ yes	☒ no

If you answered '**yes**' go to the next question. If you answered '**no**' complete the following table.

A project site address must be a street address not a postal address.

Site address 1 -where the majority of project activities will occur.

Address	Level 7, 461 Bourke Street
Suburb/ town	Melbourne
State/ territory	Victoria
Postcode	3000
Country	Australia

Site address 2

Address	Cochrane Australia, Level 4, 553 St Kilda Road
Suburb/ town	Melbourne
State/ territory	Victoria
Postcode	3004
Country	Australia

Site address 3

Address	
Suburb/ town	
State/ territory	
Postcode	
Country	Australia

C.8. Latest financial year figures

Has your organisation existed for a complete financial year?	☒ yes	☐ no
If you answered '**yes**', enter the latest completed financial year, then complete the table below.	2016-17	

Example entry 2016-17

If you answered '**no**', enter the number of months your organisation has existed, then complete the table below.	months

We collect the following data from all applicants across all grant programs. We use this data to better understand your organisation and to help us develop better policies and programs.

All amounts in the table below must show a whole dollar value e.g. $1 million should be presented as $1,000,000. The turnover value must be that of the entity that is submitting the grant (the 'applicant'), regardless of whether the entity belongs to a consolidated group for tax purposes.

These fields are mandatory and entering $0 is acceptable if applicable for your organisation.

Recent trading performance	Figures for grant the latest full financial year
Sales revenue (turnover) *Total revenue from the sale of goods and services, as reported in your organisation's Business Activity Statements (BAS).*	s47(1)(b)
Export revenue *Total revenue from export sales, as reported in your organisation's BAS.*	$0
R&D expenditure *Expenditure on research and development, i.e. creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.*	s47(1)(b)
Taxable income *Taxable income or loss as reported in your organisation's income tax return form.*	
Employees, including working proprietors and salaried directors (headcount) *Number of individuals who are entitled to paid leave (sick and holiday), or generate income from managing your organisation.*	s47F
Independent contractors (headcount) *Number of individuals engaged by your organisation under a commercial contract (rather than an employment contract) to provide employee-like services on site.*	0

C.9. Ultimate holding company

Does your company have an ultimate holding company?	☐ yes ☒ no

If you answered '**yes**' complete the following table. If you answered '**no**' go to next question.

Ultimate holding company ABN (if applicable)

Entity name of ultimate holding company *The entity name refers to the legal/ registered name that appears on official business documents. The entity name may be different from the business name.*
Country of registration of ultimate holding company

D. Project details and funding

D.1. Project title and description

If your proposal is successful, some project details will be published on GrantConnect. Published project details include:

- *name of the applicant*
- *a project title*
- *a brief project description and its intended outcomes*
- *amount of funding awarded.*

D.2. Project title and description

If your proposal is successful, some project details will be published on GrantConnect. Published project details include:

- *name of the applicant*
- *a project title*
- *a brief project description and its intended outcomes*
- *amount of funding awarded.*

Provide a project title.

This application is divided into two distinct project;

i) s22

ii) "Return to life, return to work" - a targeted clinical research investment in stroke recovery for young survivors s47(1)(b) **).**

Provide a brief project description for publication.

Ensure your project description focuses on your project's key activities and outcomes.

s22

E. Project details and funding

E.1. Project title and description

If your proposal is successful, some project details will be published on GrantConnect. Published project details include:

- *name of the applicant*
- *a project title*
- *a brief project description and its intended outcomes*
- *amount of funding awarded.*

E.2. Project title and description

If your proposal is successful, some project details will be published on GrantConnect. Published project details include:

- *name of the applicant*
- *a project title*
- *a brief project description and its intended outcomes*
- *amount of funding awarded.*

Provide a project title.

ii) "Return to life, return to work" - a targeted clinical research investment in stroke recovery for young survivors.

Provide a brief project description for publication.

Ensure your project description focuses on your project's key activities and outcomes.

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.

This package will include a clinical trial of Perispinal Etanercept in Australian stroke patients.

Currently, an estimated 142,500 (30 percent of 475,000)[4] Australian stroke survivors are of working age. International evidence shows incidence of stroke among young people is increasing[5].

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[6].

[4] Deloitte Access Economics – Impact of stroke across Australia. 2014
[5] 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.
[6] Baum C, Connor L, Morrison T, Hahn M, Dromerick A and Edwards D. Reliability, validity, and clinical utility of the executive function performance test: a measure of executive function in a sample of people with stroke. Am J Occup Ther 2008; 62: 446–455.

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 currently a gap in high quality evidence regarding the effectiveness of recovery and rehabilitation interventions following stroke in adults of working age[7].

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.

E.3. Detailed project description and key activities

Provide a detailed description of your project including the project scope and key activities.

This information will not be published.

The Stroke Foundation's Research Program funds annual research grants to promote stroke research capacity and generate new stroke knowledge. Since 2008, the Stroke Foundation has awarded nearly s47(1)(b) in research grants to more than 190 researchers.

The MRFF 'Return to life, return to work' package will be included in the 2019 Research Grant Program (calls for applications will be in July 2018, with the Grant awarded in early 2019) and will focus on clinical trials of recovery and rehabilitation interventions for stroke survivors. To be eligible for funding, proposals will be aimed at a Phase 2b, including a pathway for new indication by the Therapeutic Goods Administration (TGA).

A call for a clinical trial of Perispinal Etanercept in chronic stroke will be a key element of this 'Return to life, return to work' clinical trial program.

The research funding package will be administered by the Stroke Foundation Research Advisory Council (RAC). Specifically, the Stroke Foundation will work with the Australian Stroke Trials Network (ASTN) to ensure that all clinical trials meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable [8].

The administration of the package will reflect Australian Government standards of probity and accountability, as well as reflect the vision and strategy of the MRFF. It is a transparent, equal process ensuring investment with the greatest potential to create better health outcomes for Australians.

Clinical trial proposals will have a research plan that:

- Is well-defined, highly coherent and strongly developed.
- Is based on a clearly defined and robust scientific rationale.
- Has a near flawless study design that is sham-controlled and multi-centred.

[7] Return to work after young stroke: A systematic review Jodi D. Edwards1,2,3,4,*, Arunima Kapoor5,6,*,Elizabeth Linkewich1,5,6 and Richard H. Swartz1,2,5,6 International Journal of Stroke 2018, Vol. 13(3) 243–256

[8] Kwakkel G, et al. Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabil Neural Repair. 2017;31:793-799

- Has a clearly defined, pre-determined and accepted functional outcome measure, with assessment of neurological recovery by a team independent of the intervention team.
- Has a sample size that is based on quality randomised data.
- Adheres to industry standards including oversight by an independent data safety and monitoring committee that includes membership by neurologists/stroke specialists, rehabilitation/recovery specialists, and a biostatistician.
- Has a registered protocol and statistical analysis plan that is published, prior to unblinding of the data.
- Has a plan for open data access once the study is complete.
- Is highly feasible with all of the required expertise, research tools and techniques established.
- Has all conflicts of interest declared and is independent from the sponsor.
- Has personnel that are all GCP certified (Good Clinical Practice).
- Is highly competitive with the best, similar research proposals internationally.
- Has an accepted primary outcome measure in the field of stroke recovery that could theoretically meet TGA approval if confirmed in a large study – provided there was evidence demonstrating the need for a larger study.

4000 character limit (including spaces)

E.4. Project outcomes

Provide a summary of the expected project outcomes.

This information will not be published.

The 'Return to life, return to work' research package will support research in young stroke recovery, an emerging priority area and area of unmet need.

It has the potential to provide new treatments to those suffering from the impact of stroke.

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.

1350 character limit (including spaces)

E.5. Project milestones

Provide details on the project milestones, including the key activities occurring at each milestone.

The start date of milestone 1 is the expected project start date. The end date of your last milestone activity will be the project end date.

Milestone 1

Milestone title

Call for research applications

180 character limit (including spaces)

Milestone description

The Stroke Foundation Research Advisory Committee will call for applications that address the topic of 'Return to work, return to life' including proposals for trailing Perispinal Etanercept in chronic stroke. Independent reviewers evaluate all applications and ensure appropriate guidelines are met. The Research Advisory Committee will recommend the top ranked proposals for funding under this grant. Announcements for the successfully funded projects will be made following approval by the Board of the Stroke Foundation.

600 character limit (including spaces)

Milestone start date	Milestone end date
July 2018	December 2018

Milestone 2

Milestone title

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

180 character limit (including spaces)

Milestone description

Endorsement of each clinical trial will be sought from the Australasian Stroke Trials Network (ASTN). The ASTN comprises of leading clinicians and researchers in stroke. The ASTN assists in determining the feasibility of studies, setting appropriate recruitment forecasts and protocols. Any requirements by the ASTN to change the protocol will be made and the protocol will be finalised.

Ethics and governance approvals will be obtained. The trial will be registered on a clinical trials registry (e.g. the Australian and New Zealand Clinical Trials Registry).

Sites participating will be identified.

600 character limit (including spaces)

Milestone start date	Milestone end date
Jan 2019	June 2019

Milestone 3

Milestone title

Training of staff at trial sites

180 character limit (including spaces)

Milestone description

Staff at each identified site will be trained in undertaking the trial. This includes separate training for those administering the study and for those undertaking blinded outcome assessments. All staff will obtain certification for Good Clinical Practice (GCP).

600 character limit (including spaces)

Milestone start date	Milestone end date
Jan 2019	December 2019

Milestone 4

Milestone title

Establish Data Safety and Monitoring Committee and finalise its Charter

180 character limit (including spaces)

Milestone description

An independent Data safety and Monitoring Committee will be established. The committee will approve their Charter, and will meet when required to review the study data.

600 character limit (including spaces)

Milestone start date	Milestone end date
Jan 2019	June 2021

Milestone 5

Milestone title

Publication of study protocol and statistical analysis plan

180 character limit (including spaces)

Milestone description

The detailed study protocol will be published in an international scientific journal. The statistical analysis plan will be devised and published in an international journal prior to unblinding the group allocation.

600 character limit (including spaces)

Milestone start date	Milestone end date
June 2019	December 2020

Milestone 6

Milestone title

Patient recruitment, recruitment targets achieved

180 character limit (including spaces)

Milestone description

Patients will be recruited to the study and the targeted number of patients will be achieved.

600 character limit (including spaces)

Milestone start date	Milestone end date
June 2019	December 2020

Milestone 7

Milestone title

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

180 character limit (including spaces)

Milestone description

Patient follow-up will be finalised, and final data will be obtained from the sites and checked. All sites will be closed. The results will be analysed according to the pre-defined statistical analysis plan, and papers will be published.

600 character limit (including spaces)

Milestone start date	Milestone end date
January 2021	June 2021

E.6. Project duration

Enter your project start and end dates.

Your project start and end dates are a result of the dates you entered into your milestones. If they are not correct you will need to modify the start date for Milestone 1 and the end date for your last milestone.

Project start date	Project end date

2 July 2018	30 June 2021

E.7. Project plan

You must provide a separate project plan of the project activities you will conduct including a timetable for all significant activities.

You must include this as an attachment when submitting your proposal.

E.8. Project budget

You must attach a detailed budget indicating your eligible project costs over the life of the project. Provide a summary of your budget in the table below.

The detailed breakdown of the clinical trial budget will be determined by the successful applicants which will be independently assessed and peer reviewed. The research grants awarded under the **Return to life, return to work** will s47(1)(b) to be expended over 2 – 3 years of the this funding grant.

Amounts must be GST inclusive, less any GST credits that you can claim.

We only provide grant funding based on eligible expenditure. Refer to the guidelines for guidance on eligible expenditure.

Eligible expenditure item	FY	FY	FY	Total
Return to life, return to work research	2018-19	2019-20	2220-21	
Plant and equipment	$	$		$
Purchase of materials	$	$		$
Labour	s47(1)(b)			
Contract expenditure	$	$		$
Travel costs	$	$		$
Other eligible expenditure	s47(1)(b)			
Total				

F. Assessment criteria

You must address the following criteria and provide sufficient information for us to evaluate your proposal.

F.1. Criterion one

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.

Stroke is one of Australia's biggest causes of mortality and a leading cause of disability, it kills more women than breast cancer and more men than prostate cancer. Research has led to significant advancements in stroke, most recently the demonstrated effectiveness of endovascular clot retrieval – an example of Australian researchers leading the way internationally. Unfortunately only about 20% of ischaemic stroke patients will benefit from such hyperacute stroke therapy and other breakthroughs are needed, especially treatments applicable later in the recovery journey.

The current project will significantly advance stroke care by funding not only important clinical trial/s leading to new treatments for longer term recovery after stroke but also develop and evaluate an Australian first model of rapidly summarising new research and providing 'living' guideline recommendations. This work will put Australia's stroke health and medical research sector at the forefront of innovation, it will encourage continuous improvement and innovation benefiting all Australians and it will change lives.

The 'Return to work, return to life' research package (including the clinical trial of Perispinal Etanercept) will provide the more than 140,000 working age-Australians living with stroke and their families much needed answers. It will also benefit thousands of stroke survivors and their families into the future. There is currently 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. This package will support researchers in accelerating neurological research.

It is critical the understanding from new research trials actually impact clinical care without the time lags currently experienced. Clinical guidelines are one of the most common and important mechanisms for this translation of research into practice and policy. The current project will design, build and test enhancements to the current online tools and methods to improve efficiency and transparency of innovative 'evidence surveillance' systems. Using this system we will create and maintain 'living' guideline recommendations with input from all relevant stakeholders (including consumers). The project will importantly establish and test engagement and dissemination strategies to ensure information is shared with, and used by, busy clinicians. Finally we will thoroughly evaluate the process and impact of the living stroke guidelines system and better

understand the feasibility, acceptability and usefulness of living guidelines in Australia ensuring we provide every Australian with world class health care.

This project aligns strongly with Commonwealth Government strategy and priorities:

- World-leading research translation.
- Disruptive innovation, including machine learning and new data systems.
- Public and patient engagement in research and care (citizen science).
- Health care quality improvement.

These projects will continue to accelerate important neurological research and support Australian researchers to be at the forefront of finding solutions for stroke recovery. Furthermore, this project will create and test an Australian first model of living guidelines which will ensure clinicians, administrators and policy makers are guided in the very latest recommended practice to ensure the best recovery for those affected by stroke.

4000 character limit (including spaces)

F.2. Criterion two

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.

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 best practice 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.

Since 2008 the Stroke Foundation has managed a competitive research grants program with the guidance of the Research Advisory Committee. Members of the committee, chaired by Prof Amanda Thrift, bring substantial experience and skill in planning and conducting clinical trials and research methodology (details of committee members is available at https://strokefoundation.org.au/en/About-us/Governance/Research-Advisory-Committee). The Stroke Foundation will work with the Australian Stroke Trials Network (ASTN) to ensure that all clinical trials meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA), thus ensuring projects are led and supported by researchers who have the skills and experience to deliver ground breaking research.

Stroke Foundation is recognised as one of the most experience developers of National Health and Medical Research Council (NHMRC) approved guidelines and a global leader in stroke clinical management guidelines. The Stroke Foundation has been producing NHMRC approved guidelines since 2005 and most recently (2017) were one of the first organisations to develop and publish clinical guidelines online using the MAGICapp platform which also uses the internationally recognised leading methodology of the GRADE approach. The Stroke Foundation therefore has

extensive track record of managing high level projects. Our experience, as outlined in this application, will ensure the right people, technology, project methodology and financial management practices are used. Stroke Foundation will provide significant in-kind support in the form of senior staff time and use of the National Stroke Audit in the evaluation of the project.

4000 character limit (including spaces)

G. Assessment criteria

You must address the following criteria and provide sufficient information for us to evaluate your proposal.

G.1. Criterion one

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.

As in F.1

4000 character limit (including spaces)

G.2. Criterion two

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.

As in F.2

4000 character limit (including spaces)

H. Supporting documents

You should note any supporting documentation that you attach to the proposal here. You should only attach documents you have referred to in your proposal.

The following restrictions apply to attachments:

- *total size of all attachments and this form should not exceed 20MB*
- *file size of each attachment cannot exceed 2MB*
- *only files with the following file type extension can be uploaded (.pdf, .rdtf, .doc, .docx, .xls, .xlsx)*

For assistance with any technical issues experienced while completing this application form or attaching documents phone 13 28 46. Our staff can help you.

H.1. Attachment 01 – Incorporated trustees

This attachment is mandatory only for applicants where an incorporated trustee is applying on behalf of a trust.

Part of application form	Type of attachments	Attached?
Part C3 - Trustee and trust details	Trust documents showing the relationship of the incorporated trustee to the trust.	☐ yes

H.2. Attachment 02 – Project plan including timetable

Part of application form	Type of attachments	Attached?
Part D3 – Project plan	A plan of the project activities you will conduct including a timetable for all significant activities.	☒ yes

H.3. Attachment 03 – Project budget

Part of application form	Type of attachments	Attached?
Part D4 – Project budget	A detailed budget demonstrating the cost of the eligible activities and delineating any ineligible activities.	☒ yes

I. Applicant declaration

I.1. Conflicts of interest

Do you have any perceived or existing conflicts of interest to declare? ☐ yes ☒ no

Refer to the [program/grant opportunity] guidelines for further information on your conflict of interest responsibilities.

If yes, describe the perceived or existing conflict/s of interest and how you anticipate managing them.

750 character limit (including spaces)

I.2. Privacy and confidentiality provisions

I acknowledge that this is an Australian Government program and that the department will use the information I provide in accordance with the following

- Australian Government Public Data Policy Statement
- Commonwealth Grants Rules and Guidelines
- grant opportunity guidelines
- applicable Australian laws.

Accordingly, I understand that the department may share my personal information provided in this application within this department and other government agencies:

g. for purposes directly related to administering the program, including governance, research and the distribution of funds to successful applicants and

h. to facilitate research, assessment, monitoring and analysis of other programs and activities

unless otherwise prohibited by law.

I understand that where I am successful in obtaining a grant, the financial information that I provide for the purposes of payment will be accessible to departmental staff to enable payments to be made through the department's accounts payable software system.

I understand that information that is deemed 'confidential' in accordance with the guidelines may also be shared for a relevant Commonwealth purpose.

The department will publish information on individual grants in the public domain, including on the department's website, unless otherwise prohibited by law.

I.3. Applicant declaration

I declare that I have read and understood the [program/grant opportunity] guidelines, including the privacy, confidentiality and disclosure provisions.

I declare that the proposed project outlined in this application and any associated expenditure has been endorsed by the applicant's Board or person with authority to commit the applicant to this project.

I declare that the applicant will comply with, and require that its subcontractors and independent contractors comply with, all applicable laws.

I declare that the information contained in this application together with any statement provided is, to the best of my knowledge, accurate, complete and not misleading and that I understand that giving of false or misleading information is a serious offence under the *Criminal Code 1995* (Cth).

I acknowledge that I may be requested to provide further clarification or documentation to verify the information supplied in this form and that the department may, during the application process, consult with other government agencies, including state and territory government agencies, about the applicant's claims and may also engage external technical or financial advisors to advise on information provided in the application.

I acknowledge that if the department is satisfied that any statement made in an application is incorrect, incomplete, false or misleading the department may, at its absolute discretion, take appropriate action. I note such action may include excluding an application from further consideration; withdrawing an offer of funding; using the information contained in the application for a fraud investigation that would be consistent with the Australian Government's Investigations Standard and Commonwealth Fraud Control Framework and for management purposes and/or terminating any grant agreement between the Commonwealth and the recipient including recovering funds already paid.

I agree to participate in the periodic evaluation of the services undertaken by the department.

I declare that I am authorised to complete this form and acknowledge that by including my name in this application I am deemed to have signed this application.

I approve the information in this application being communicated to the department in electronic form.

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

I.4. Signature

Name of signatory	s47F
Email address of signatory	s47F @strokefoundation.org.au
Date	31 May 2018
Signature	s47F

s22

From: Accelerated Research Program <arp@industry.gov.au>
Sent: Monday, 26 September 2022 8:32 AM
To: s22 ; Accelerated Research Program; s22
Cc: s22
Subject: RE: TRIM: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22

Thanks for the advice. s22

I will get it to you as soon as possible

Thanks

s22

From: s22 @Health.gov.au]
Sent: Wednesday, 21 September 2022 4:48 PM
To: Accelerated Research Program <arp@industry.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Subject: RE: TRIM: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22

Thank you for your email.

All variations to the grant agreement should be reflected in the BGH minute.

This is for the purpose of consistency across all variation documents (i.e. BGH minute, draft Variation Contract, HMRO minute, etc.) that will be presented to the Delegate for consideration.

s22

Regarding timeframes, we understand public holidays and BGH capacity may influence this, so at your earliest convenience is fine.

Thank you.

Best regards,

s22

Emerging Priorities and Researchers Section
Health and Medical Research Office
Department of Health and Aged Care
s22

From: Accelerated Research Program <arp@industry.gov.au>
Sent: Wednesday, 21 September 2022 4:00 PM
To: s22 @Health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Subject: RE: TRIM: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22

s22

We have public holidays here and so I won't be back until Monday. Hopefully the grantee will have responded by then.

Are you asking for us to provide a new minute, all the attachments plus attach the email from the grantee justifying the new date as a new package?

This will take some time and I am unsure how this additional work will affect the outcome.

Thanks

s22

OFFICIAL

From: s22 @Health.gov.au]
Sent: Wednesday, 21 September 2022 3:21 PM
To: Accelerated Research Program <arp@industry.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @industry.gov.au>
Subject: RE: TRIM: RE: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22

Thank you for providing the updated Variation Contract.

s22

Can we please ask that BGH resubmit the variation package to reflect this change (including justification), and all other changes so that they will align with the minute.

Ideally, we would like to receive the updated variation package at your earliest convenience to keep the request moving.

Please let myself or s22 know if you have any questions.

Best regards,

s22

Emerging Priorities and Researchers Section
Health and Medical Research Office
Department of Health and Aged Care
s22

From: Accelerated Research Program <arp@industry.gov.au>
Sent: Tuesday, 20 September 2022 10:08 AM
To: s22 @health.gov.au>; s22 @industry.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; s22 @Health.gov.au>; s22 @industry.gov.au>
Subject: TRIM: RE: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22

Please find attached an amended variation for The National Stroke Foundation which splits *Return to Life (PESTO)* and *Return to Work* into two schedules. The grantee has amended the milestones for *Return to Life (PESTO)*. s22

Please do not hesitate to contact me if you require further information or clarification

Kind Regards

s22

OFFICIAL

From: s22 @health.gov.au]
Sent: Friday, 9 September 2022 3:58 PM
To: s22 @industry.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; s22 @Health.gov.au>; s22 @industry.gov.au>
Subject: RE: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22
Lovely to speak with you this morning.

As discussed, given the way that the grant was originally written and that the Activity Schedule covers both of the activities for Return to work (RTW) and Return to life (RTL), we suggest that these two components have separate headings and Activity Schedules in the Variation contract as the RTW project is now on track despite experiencing delays in 2021 s22 .

If you could get back to us as soon as you can as we expect to commence our QA process next week.

With thanks,
s22

From: s22 @industry.gov.au>
Sent: Friday, 19 August 2022 12:56 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; Accelerated Research Program <arp@industry.gov.au>; s22 @Health.gov.au>; s22 @industry.gov.au>
Subject: EPCD000019 - National Stroke Foundation - Variation Request [SEC=OFFICIAL]

Hi s22 and team

Please find attached variation approval minute and variation request documentation for EPCD000019 –National Stroke Foundation - Project titled 'Guidelines for Stroke Management and Return to life, return to work - recovery for young survivors'.

Referring to the grant variation policy, the grantee is requesting:

2. Defer an in-progress grant variation
A 12-month, no cost deferment of grant milestones extending the project end date to 31 December 2023.

Attached are the following documents:

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

Please let me know if you need anything else.

Kind regards

s22
Vic Program Management & Delivery / Business Grants Hub
Department of Industry, Science and Resources
T (03) s22 @industry.gov.au

Acknowledgement of Country

Our department recognises the First Peoples of this nation and their ongoing connection to culture and country. We acknowledge First Nations Peoples as the Traditional Owners, Custodians and Lore Keepers of the world's oldest living culture and pay respects to their Elders past, present and emerging.

OFFICIAL

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