

s22

From: s22
Sent: Friday, 4 June 2021 10:20 AM
To: Accelerated Research Program; s22
Cc: s22
Subject: RE: National Stroke Foundation - 'Return to life, return to work' clinical trials - Application ID: EPCD000019 (ARG73055) [SEC=OFFICIAL]

Hi s22,

Could you please provide the National Stroke Foundation with our response regarding the use of overseas clinical trials for the 'Return to life, return to work' clinical trials. The org will need to continue to explain and highlight the benefits to Australians by having international sites in their annual grant reporting.

Thanks,
s22

Dear s47F

Thank you for the information about the overseas sites for the PESTO trial.

The Medical Research Future Fund Act 2015 (the Act) indicates that the MRFF (Section 3) was established to improve the health and wellbeing of Australians by providing grants of financial assistance to support medical research and medical innovation. We consider that this objective is best supported in most circumstances by medical research and medical innovation undertaken in Australia, by an Australian body, with the participation of the Australian community. However, we note the factors for the PESTO NZ and UK sites and you have explained in your written response on 12 May 2021 how this research will benefit Australians. We also note that the populations at these sites are similar to Australians and results may be able to be extrapolated to Australian populations. Please continue to explain and highlight these benefits to Australians in your grant reporting.

Regards,
BGH

From: Accelerated Research Program
Sent: Thursday, 13 May 2021 10:27 AM
To: s22
Cc: s22 ; Accelerated Research Program
Subject: FW: National Stroke Foundation - 'Return to life, return to work' clinical trials - Application ID: EPCD000019 (ARG73055) [SEC=OFFICIAL]

Dear s22

Please find National Stroke's response to the use of overseas clinical trials. The answer is yes but the current outlay is minor with a view for a substantial increase. National Stroke has articulated the reasons for conducting the trials overseas.

Please advise next steps.

Thanks
s22

OFFICIAL

From: Research [<mailto:research@strokefoundation.org.au>]
Sent: Wednesday, 12 May 2021 3:07 PM
To: Accelerated Research Program <arp@industry.gov.au>
Cc: s47F [redacted] <s47f@strokefoundation.org.au>
Subject: National Stroke Foundation - 'Return to life, return to work' clinical trials - Application ID: EPCD000019 (ARG73055)

Dear s22 [redacted]

Please find attached a letter in response to your advice regarding information required for the Department of Health, following the meeting held on 3 May 2021 regarding the 'Return to life, return to work' clinical trials, and specifically addressing PESTO trial international sites.

Please do not hesitate to reach out to us if you need any further clarification.

Thank you in advance for sharing this with the Department and we look forward to your response.

Warm regards,

s47F

Research Administration & Compliance Officer

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC3000

D 03 s47F [redacted]

StrokeLine: 1800 STROKE (1800 787 653)

research@strokefoundation.org.au

Stroke Foundation

StrokeLine: 1800 STROKE (1800 787 653)



This document has been released under
 the Freedom of Information Act 1982
 by the Department of Health, Disability and Ageing

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





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

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

This document has been released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

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

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

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

Context of PESTO trial and trial design

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

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

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

Selection of sites

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

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

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

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

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

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

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

The fixed set-up cost for the New Zealand site is \$^{s47(1)(b)} and total per patient cost is \$^{s47(1)(b)} (this is the averaged cost of patients treated with placebo and patients who receive the active treatment). The NZ site has enrolled 18 patients to date (April 2021) thus incurring \$^{s47(1)(b)} of eligible project expenses under the grant. We anticipate that they will achieve the required 50 patients enrolled by the end of the recruitment period for this project.

International significance of outcomes of PESTO trial

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

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

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

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

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

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

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

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

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

Sincerely,

S47F

Chief Executive Officer
Stroke Foundation

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

From: s47F [redacted]@strokefoundation.org.au>
Sent: Tuesday, 21 July 2020 5:46 PM
To: s22 [redacted];
 Accelerated Research Program
Cc: s22 [redacted]
Subject: Re: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

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

No problem. See below. If that is not suitable or if you need more please let me know.

s22

Get [Outlook for iOS](#)

s47F [redacted]
 National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F [redacted]

StrokeLine: 1800 STROKE (1800 787 653)

s47F [redacted] [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)

Email Confidentiality Statement

From: s22 [redacted]@health.gov.au>
Sent: Tuesday, July 21, 2020 4:58:08 PM
To: s47F [redacted]@strokefoundation.org.au>; s22 [redacted]
 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]
 [redacted]@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 [redacted]@industry.gov.au>
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

Hi s47F [redacted]

Thanks for your prompt reply.

s22

Many thanks,
 s22 [redacted]

From: s47F [redacted]@strokefoundation.org.au>
Sent: Tuesday, 21 July 2020 4:34 PM
To: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 [redacted]@industry.gov.au>
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

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

Hi s22 [redacted]

The email address remains the best contact.

Hopefully I will have an update that the trial is progressing soon.

s47F

National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F [redacted]

StrokeLine: 1800 STROKE (1800 787 653)

s47F [redacted]@strokefoundation.org.au

Email Confidentiality Statement

From: s22 [redacted]@health.gov.au>
Sent: Tuesday, 21 July 2020 4:32 PM
To: s47F [redacted]@strokefoundation.org.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 [redacted]@industry.gov.au>
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

Hi s47F [redacted]

Thank you for informing the Department that the PESTO trial has been placed on hold. Please keep us updated on this progress and how this may impact on recruitment numbers and the expected completion date for the trial.

On a separate but related matter, we received an enquiry about the PESTO trial and how to gain access to perispinal etanercept treatment. Previously, you have provided us with an email address where members of the public can register their interest or participation by s22 [redacted]. Is this still the best way for people to register their interest?

Many thanks,

s22

Assistant Director

Emerging Priorities and Researchers Section

Health and Medical Research Office

Ph: (s22 [redacted])

From: s47F [redacted] <[\[redacted\]@strokefoundation.org.au](mailto:[redacted]@strokefoundation.org.au)>
Sent: Tuesday, 21 July 2020 2:19 PM
To: s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>; s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>; s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>; s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 [redacted] <[\[redacted\]@industry.gov.au](mailto:[redacted]@industry.gov.au)>
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

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

Afternoon all,

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

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

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

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

If I can provide additional details please let me know.

Stay well and safe!

s47F

ger, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F

StrokeLine: 1800 STROKE (1800 787 653)

s47F <[\[redacted\]@strokefoundation.org.au](mailto:[redacted]@strokefoundation.org.au)>

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





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

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

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

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

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

From: s47F [redacted]@strokefoundation.org.au>
Sent: Tuesday, 10 March 2020 4:01 PM
To: s22 [redacted];
 Accelerated Research Program
Cc: s22 [redacted]
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

Hi all,

Just an update, on March 6 the PESTO trial received Austin Research Governance Office approval.

Recruitment has now commenced.

As discussed previously, expressions of interest for participation in the trial are held by the research team. A mailbox for the trial has been provided s22 [redacted] through which the research team are managing inquiries for the trial directly. If you have any queries please pass on the email address.

Thanks and if I can provide any further detail please let me know,

s47F

National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F [redacted]

StrokeLine: 1800 STROKE (1800 787 653)

s47F [redacted] [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)

Email Confidentiality Statement

From: s47F [redacted]
Sent: Monday, 2 March 2020 4:45 PM
To: s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 [redacted]@industry.gov.au>
Subject: RE: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]

Hi all,

Thanks for taking the time to meet today.

Please see attached FYR.

If you would like additional details or I can assist further please let me know,

s47F

-----Original Appointment-----

From: s22 [redacted] [@health.gov.au](mailto:s22@health.gov.au)>
Sent: Tuesday, 25 February 2020 9:55 AM
To: s22 [redacted]; s47F [redacted] [@florey.edu.au](mailto:s47F@florey.edu.au); s47F [redacted] [@monash.edu](mailto:s47F@monash.edu);

s47F ;s22 ; Accelerated Research Program
Cc: s47F@gmail.com; s22
Subject: MRFF Teleconference - National Stroke Foundation [SEC=OFFICIAL]
When: Monday, 2 March 2020 4:10 PM-4:40 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where:

Hi Everyone,

The purpose of this teleconference to discuss progress on funded activities and to help build our understanding of the projects currently underway.

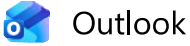
Please use the participant details below to call into the teleconference.

OHMR Line 1
Dial: 1800 701 826
Moderator Passcode: 5176 1938
Participant passcode: 8184 4575

Regards,
s22

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

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing



RE: Return to life, return to work update [SEC=OFFICIAL]

From s22@health.gov.au>
Date Thu 1/16/2020 3:45 PM
To s47F@strokefoundation.org.au
Cc s22@health.gov.au>; s22@health.gov.au>; s22@health.gov.au>

Hi s47F

Thanks for providing the information on the progress of the two projects. Are you able to provide any insight as to why there is delays in obtaining Governance Approval for the PESTO project?

Regards,

s22

From: s47F@strokefoundation.org.au
Sent: Thursday, 16 January 2020 9:51 AM
To: s22@health.gov.au>
Cc: s22@health.gov.au>; s22@health.gov.au>; s22@health.gov.au>
Subject: RE: Return to life, return to work update [SEC=OFFICIAL]

Hi s22

Apologies for the delay in getting this to you. I wanted to make sure I had all the correct info.

The full amounts awarded for each grant recipient are (for 2019-2021):

- Professor Vincent Thijs, Florey Institute of Neuroscience and Mental Health - Perispinal Etanercept to improve Stroke Outcomes (PESTO)

s47(1)(b)

s22

The first year instalments (based on Year 1 budgets from their applications) released in 2019 to each were:

- Perispinal Etanercept to improve Stroke Outcomes (PESTO)

s47(1)(b)

s22

(Amounts above are ex GST. GST does apply to the grants)

Regarding recruitment for the PESTO trial, there has been a delay with receiving Austin Research Governance Office approval (submitted on 24/09/2019), pending approval. The research team expect this approval to be granted by end of January 2020. Once this has occurred, recruitment can commence, this is anticipated for February 2020. Expressions of interest for participation in the trial are held by the research team, and from

the start of 2020, a mailbox for the trial has been provided s22 through which the research team are managing inquiries for the trial directly.

s22

If I can assist further please let me know. My understanding is the next report will be submitted to the Department at the end of the month.

When I have any additional updates I will send them through.

Have a good day,

s47F

National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F

Stroke line: 1800 STROKE (1800 787 653)

s47F [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)

Email Confidentiality Statement

From: s22 [@health.gov.au](mailto:s22@health.gov.au)>

Sent: Wednesday, 15 January 2020 9:22 AM

To: s47F [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)>

Cc: s22 [@health.gov.au](mailto:s22@health.gov.au)>; s22

s22 [@health.gov.au](mailto:s22@health.gov.au)>; s22 [@health.gov.au](mailto:s22@health.gov.au)>

Subject: Return to life, return to work update [SEC=OFFICIAL]

Hi s47F

I hope this email finds you well.

I am writing to seek some further information in relation to the Return to life, return to work research package.

In the last progress report we received, we understand that the Return to life, return to work research was split into two components s47(1)(b) for the perispinal etanercept trial and s47(1)(b) for the return to work for younger stroke survivors.

On 15 March 2019, the National Stroke Foundation notified Business Grants Hub that two successful recipients for the Return to work, Return to Life grant had been confirmed:

- Professor Vincent Thijs, Florey Institute of Neuroscience and Mental Health - Perispinal Etanercept to improve Stroke Outcomes (PESTO)

s22

Are you able to confirm the amounts which the two successful amounts received?

Also in relation to the PESTO project, in an update you provided in July 2019, you advised that the research protocol was being finalised and that recruitment of patients was expected to commence in October 2019. Could you please confirm if the project has commenced recruitment?

Greatly appreciate if you could get back to us as soon as possible. I am not in the office today but my colleagues s22 (who have been copied into this email) may follow up with you today.

Kind regards,

s22

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

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

From: s47F [redacted]@strokefoundation.org.au>
Sent: Tuesday, 16 July 2019 11:02 AM
To: s22 [redacted]
Cc: s22 [redacted]
Subject: Etanercept trial [SEC=No Protective Marking]

Hi s22

I received an update from the Entanercept trial team today so thought I would send through an updated response in case you were getting queries too:

July 2019: The protocol is being finalised based on the recommendations from the ethics committee and the steering committee. Subsequent to that, the trial has to go through governance process at the individual hospitals. The research team anticipate the first enrollment in October 2019. The research team will contact people who have expressed interest then.

If you would like to register contact research@strokefoundation.org.au.

If you would like to speak with a health professional in the meantime, please call the Stroke Foundation StrokeLine team on 1800 787 653.

Thanks mate, I'll let you know if I hear anymore.

s47F

National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne, VIC, 3000

D 03 s47F

StrokeLine: 1800 STROKE (1800 787 653)

s47F [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)



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


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

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

 Outlook

National Stroke Overseas Clinical Trial [SEC=OFFICIAL]

From s22 @industry.gov.au>
Date Wed 4/21/2021 11:08 AM
To s22 @health.gov.au>
Cc s22 @industry.gov.au>; Accelerated Research Program <arp@industry.gov.au>

 1 attachment (11 MB)

National Stroke Foundation - Evidence of Activity January 2020.pdf;

Hi s22

In relation to the UK clinical trial, so far I found the following:

- No active communication from the grantee regarding conducting a UK trial;
- The Jan 2020 progress report assessment mentions that part of the difficulty in recruiting patients for the trial is because there was another Stroke clinical trial running concurrently, perhaps this prompted the UK trial; and
- Please see the attachment – Evidence of Activity January 2020, where on page 12 of 62: It states at 5. Other relevant information..... : Approximately 168 participants will be involved in this study. This study is being conducted in hospitals in Australia and **the UK**.

Preliminary conclusion: It appears all of us missed this detail about the UK trial. Therefore Grantee did tell us but not explicitly and did not ask prior permission based on what I can find. Anyway, I have asked the grantee to provide an explanation as to why UK was used and now New Zealand to conduct clinical trials. We should find out more soon or at the teleconference.

Thanks

s22

OFFICIAL



Perispinal Etanercept Clinical Trial Grant Application Form

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)	Vincent Thijs	
Applicant Email:	s47F @florey.edu.au	
Research Question:	Does Perispinal Etanercept (PSE) promote recovery after chronic stroke in Australian stroke survivors of working age?	<input checked="" type="checkbox"/>
Research Project Title	Perispinal Etanercept to improve STroke Outcomes (PESTO)	
Funding requested: (Up to a maximum value of s47(1)(b) exc GST over 2.5 years)	s47(1)(b)	
Administering Organisation (Contact person must not be Applicant)	<p>Contact person: s47F</p> <p>Name of institution: Florey Institute of Neuroscience and Mental Health</p> <p>Postal address for contact person: 30 Royal Parade, Parkville, VIC 3052</p> <p>Email of contact person: RAO@florey.edu.au</p> <p>ABN of institution: 92 124 762 027</p>	

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.

s47(1)(b)

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

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

Yes No

Please provide relevant details below



Perispinal Etanercept Clinical Trial Grant Application Form

1.3 Consumer Engagement

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

Yes

No

An experienced trials consumer (stroke survivor) forms part of this team. She has consulted on the protocol and provided feedback and will serve on the trial Steering Committee.

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)	Professor Vincent Thijs	Stroke theme, Florey Institute of Neuroscience and Mental Health,
Chief Investigator B	S47F	Stroke theme, Florey Institute of Neuroscience and Mental Health,
Chief Investigator C		Faculty of Health Sciences and Medicine, University of Nottingham, United Kingdom
Chief Investigator D		Stroke Medicine, Alfred Health
Chief Investigator E		Florey Institute of Neuroscience and Mental Health,
Chief Investigator F		Stroke consumer, Melbourne
Chief Investigator G		Faculty of Health Sciences and Medicine, University of Nottingham, United Kingdom
Chief Investigator H		Faculty of Health Sciences and Medicine, University of Nottingham, United Kingdom



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).

s47(1)(b)

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

Perispinal Etanercept Clinical Trial Grant Application Form

s47(1)(b)

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. Protocol and informed consent finalised, submitted to ethics- by March 2019

Final protocol written and approved by steering committee. Patient information and informed consent forms finalised. Trial material submitted to ethics committee

2. 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)

3. 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.

4. Training of staff at trial sites – by December 2019

Staff at 4 sites 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). First site likely to be initiated in July 2019



Perispinal Etanercept Clinical Trial Grant Application Form

5. First 50 patients enrolled –by January 2020

6. First 100 patients enrolled- by June 2020

7. 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.

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

9. Last patient final follow-up-by 28 Feb 2021

10. 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.

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing



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)

CIA: Professor Vincent Thijs

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

TOP 5 PUBLICATIONS IN THE LAST 5 YEARS:

1. Brainstorm Consortium. Analysis of shared heritability in common disorders of the brain. *Science*. 2018;360
2. Dewilde S, Annemans L, Peeters A, Hemelsoet D, Vandermeeren Y, Desfontaines P, Brouns R, Vanhooren G, Cras P, Michielsens B, Redondo P, Thijs V. Modified Rankin scale as a determinant of direct medical costs after stroke. *Int J Stroke*. 2017;12:392-400
3. Thijs V, Grittner U, Dichgans M, Enzinger C, Fazekas F, Giese AK, Kessler C, Kolodny E, Kropp P, Martus P, Norrving B, Ringelstein EB, Rothwell PM, Schmidt R, Tanislav C, Tatlisumak T, von Sarnowski B, Rolfs A, Stroke in Fabry I. Family History in Young Patients With Stroke. *Stroke*. 2015;46:1975-1978



Perispinal Etanercept Clinical Trial Grant Application Form

4. Meyer S, Verheyden G, Brinkmann N, Dejaeger E, De Weerd W, Feys H, Gantenbein AR, Jenni W, Laenen A, Lincoln N, Putman K, Schuback B, Schupp W, Thijs V, De Wit L. Functional and motor outcome 5 years after stroke is equivalent to outcome at 2 months: follow-up of the collaborative evaluation of rehabilitation in stroke across Europe. *Stroke*. 2015;46:1613-1619
5. Thomalla G, Simonsen CZ, Boutitie F, Andersen G, Berthezene Y, Cheng B, Cheripelli B, Cho TH, Fazekas F, Fiehler J, Ford I, Galinovic I, Gellissen S, Golsari A, Gregori J, Gunther M, Guibernau J, Hausler KG, Hennerici M, Kemmling A, Marstrand J, Modrau B, Neeb L, Perez de la Ossa N, Puig J, Ringleb P, Roy P, Scheel E, Schonewille W, Serena J, Sunaert S, Villringer K, Wouters A, Thijs V, Ebinger M, Endres M, Fiebach JB, Lemmens R, Muir KW, Nighoghossian N, Pedraza S, Gerloff C, Investigators W-U. MRI-Guided Thrombolysis for Stroke with Unknown Time of Onset. *N Engl J Med*. 2018;379:611-622

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

Perispinal Etanercept Clinical Trial Grant Application Form

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

S47F

Top 5 Publications

1. Godecke, E., Rai, T., Cadilhac, D. A., Armstrong, E., Middleton, S., Ciccone, N., . . . **Bernhardt, J.** (2018). Statistical analysis plan (SAP) for the Very Early Rehabilitation in Speech (VERSE) after stroke trial: an international 3-arm clinical trial to determine the effectiveness of early, intensive, prescribed, direct aphasia therapy. *International Journal of Stroke*, 13(8), 863-880. doi:10.1177/1747493018790055
2. Cumming, T., Lowe, D., Linden, T., **Bernhardt, J.** on behalf of the AVERT Investigators Group. (2018). The AVERT MoCA Data: Scoring Reliability in a Large Multicenter Trial. *Assessment*, (ePub 7 Jun 18)
3. **Bernhardt J**, Churilov L, Ellery F, Collier J, Chamberlain J, Langhorne P, et al. Pre-specified dose response analysis for A Very Early Rehabilitation Trial (AVERT). *Neurology* 2016;86(23):2138-45 (ePub February 17, 2016)
4. **Bernhardt J**, et al on behalf of the AVERT trial collaboration. Efficacy and safety of very early mobilisation after stroke (AVERT): A randomised controlled trial. *The Lancet* 2015;386(9988):46-55.
5. Kwakkel G, Lannin NA, Borschmann K, English C, Ali M, Churilov L, .. and **Bernhardt J**. Standardized Measurement of Sensorimotor Recovery in Stroke Trials: Consensus-Based Core Recommendations from the Stroke Recovery and Rehabilitation Roundtable. *Neurorehabilitation and Neural Repair*. 2017;31(9):784-92.

S47F



Perispinal Etanercept Clinical Trial Grant Application Form

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

Perispinal Etanercept Clinical Trial Grant Application Form

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

S47F

Top 5 Publications

1. Sprigg N, Flaherty K, Appleton JP, Al-Shahi Salman R, Bereczki D, Beridze M, Christensen H, Ciccone A, Collins R, Czlonkowska A, Dineen RA, Duley L, Egea-Guerrero JJ, England TJ, Krishnan K, Laska AC, Law ZK, Ozturk S, Pocock SJ, Roberts I, Robinson TG, Roffe C, Seiffge D, Scutt P, Thanabalan J, Werring D, Whynes D, Bath PM, Investigators T-. Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage (TICH-2): an international randomised, placebo-controlled, phase 3 superiority trial. *Lancet*. 2018;391:2107-2115
2. Bath PM, Woodhouse LJ, Appleton JP, Beridze M, Christensen H, Dineen RA, Duley L, England TJ, Flaherty K, Havard D, Heptinstall S, James M, Krishnan K, Markus HS, Montgomery AA, Pocock SJ, Randall M, Ranta A, Robinson TG, Scutt P, Venables GS, Sprigg N, Investigators T. Antiplatelet therapy with aspirin, clopidogrel, and dipyridamole versus clopidogrel alone or aspirin and dipyridamole in patients with acute cerebral ischaemia (TARDIS): a randomised, open-label, phase 3 superiority trial. *Lancet*. 2018;391:850-859
3. Berge E, Al-Shahi Salman R, van der Worp HB, Stapf C, Sandercock P, Sprigg N, Macleod MR, Kelly PJ, Nederkorn PJ, Ford GA, European Stroke Organisation Trials Network C. Increasing value and reducing waste in stroke research. *Lancet Neurol*. 2017;16:399-408
4. England TJ, Hedstrom A, O'Sullivan S, Donnelly R, Barrett DA, Sarmad S, Sprigg N, Bath PM. RECAST (Remote Ischemic Conditioning After Stroke Trial): A Pilot Randomized Placebo Controlled Phase II Trial in Acute Ischemic Stroke. *Stroke*. 2017;48:1412-1415
5. Sprigg N, O'Connor R, Woodhouse L, Krishnan K, England TJ, Connell LA, Walker MF, Bath PM. Granulocyte Colony Stimulating Factor and Physiotherapy after Stroke: Results of a Feasibility Randomised Controlled Trial: Stem Cell Trial of Recovery EnhanceMent after Stroke-3 (STEMS-3 ISRCTN16714730). *PLoS One*. 2016;11:e016135

Perispinal Etanercept Clinical Trial Grant Application Form

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

S47F

Top 5 Publications in the last 5 years and reason for choice:

1. Creamer M, **Cloud G**, et al. Intrathecal baclofen therapy versus conventional medical management for severe poststroke spasticity: results from a multicentre, randomised, controlled, open-label trial (SISTERS). J Neurol Neurosurg Psychiatry. 2018 Jan 11. pii: jnnp-2017-317021. doi: 10.1136/jnnp-2017-317021.
2. Michael Creamer, **Geoffrey Cloud**, et al. Effect of Intrathecal Baclofen on Pain and Quality of Life in Post stroke Spasticity. A Randomized Trial (SISTERS). Originally published 14 Aug 2018 Stroke. 2018; 49:2129–213. Bruce CV Campbell, ..., **Geoffrey Cloud**, et al for the Hermes collaborators. Penumbra imaging and functional outcome in patients with anterior circulation ischaemic stroke treated with endovascular thrombectomy versus medical therapy: a meta-analysis of individual patient-level data. Lancet Neurol. 2018 Nov 6. pii: S1474-4422(18)30314-4. doi: 10.1016/S1474-4422(18)30314-4.
3. Bray BD, **Cloud GC**, et al. SSNAP collaboration. Weekly variation in health-care quality by day and time of admission: a nationwide, registry-based, prospective cohort study of acute stroke care. Lancet. 2016 May 10. pii: S0140-6736(16)30443-3. doi: 10.1016/S0140-6736(16)30443-3.
4. Bray BD, Ayis S, Campbell J, **Cloud GC**, James M, Hoffman A, Tyrrell PJ, Wolfe CD, Rudd AG. Associations between Stroke Mortality and Weekend Working by Stroke Specialist Physicians and Registered Nurses: Prospective Multicentre Cohort Study. PLoS Med. 2014 Aug 19; 11(8):e1001705. doi: 10.1371/journal.pmed.1001705.

S47F



Perispinal Etanercept Clinical Trial Grant Application Form

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

Perispinal Etanercept Clinical Trial Grant Application Form

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

S47F

Top 5 Publications in the last 5 years

Campbell BCV, Mitchell PJ, **Churilov L**, Parsons MW, Donnan GA, Davis SM et al. (2018). Tenecteplase versus alteplase before thrombectomy for ischemic stroke. *The New England Journal of Medicine* 2018

Campbell, BCV, Mitchell, PJ, Kleinig, TJ, Dewey, HM, **Churilov, L**, et al (2015). Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection. *The New England Journal of Medicine*. 372:1009-1018.

Bernhardt, J, Langhorne P, Lindley, R, Thrift, AG, Ellery, F, Collier, J, **Churilov, L**, Moodie, M, Dewey, HM, & Donnan, GA, for The AVERT Trial Collaboration group (2015). Efficacy and safety of very early mobilisation within 24h of stroke onset (AVERT): a randomised controlled trial. *The Lancet*. 386(9988): 46–55.

Campbell BCV, Christensen S, Parsons MW, **Churilov L**, et al. (2013). Advanced Imaging Improves Prediction of Hemorrhage after Stroke Thrombolysis. *Annals of Neurology* 73(4):510-519.

Meretoja A, Keshkaran M, Saver JL, Tatlisumak T, Parsons MW, Kaste M, Davis SM, Donnan GA, & **Churilov L**. (2014). Stroke Thrombolysis. Save a Minute – Save a Day. *Stroke* 45: 1053-1058.

S47F



Perispinal Etanercept Clinical Trial Grant Application Form

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing



Perispinal Etanercept Clinical Trial Grant Application Form

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

s47F

Publications:

1. Bernhardt J, Churilov L, Ellery F, Collier J, Chamberlain J, Langhorne P, et al. Pre-specified dose response analysis for A Very Early Rehabilitation Trial (AVERT). *Neurology* 2016;86(23):2138-45 (ePub February 17, 2016)
2. Bernhardt J, et al on behalf of the AVERT trial collaboration. Efficacy and safety of very early mobilisation after stroke (AVERT): A randomised controlled trial. *The Lancet* 2015;386(9988):46-55.
3. Cumming, T., Lowe, D., Linden, T., Bernhardt, J. on behalf of the AVERT Investigators Group. (2018). The AVERT MoCA Data: Scoring Reliability in a Large Multicenter Trial. *Assessment*, (ePub 7 Jun 18)
4. Cumming, T., Bernhardt, J., Lowe, D., Collier, J., Dewey, H., Langhorne, P., . . . on behalf of the AVERT Trial Collaboration group. (2018). Early mobilization after stroke is not associated with cognitive outcome: Findings from AVERT. *Stroke*. ;49:2147-215
5. Bernhardt J, Churilov L, Dewey H, Lindley R, Moodie M, Collier J, Langhorne P, Thrift A, Donnan G. Statistical analysis plan (SAP) for A Very Early Rehabilitation Trial (AVERT): an international trial to determine the efficacy and safety of commencing out of bed standing and walking training (very early mobilisation) within 24 h of stroke onset vs usual stroke unit care. *International Journal of Stroke* 2015;10:23-24

This document has been released under
the Freedom of Information Act
by the Department of Health

Perispinal Etanercept Clinical Trial Grant Application Form

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

s47F

Top 5 publications in the last five years:

1. Lindley RI, Anderson CS, Billot L, Forster A, Hackett ML, Harvey LA, Jan S, Qiang L, Langhorne P, Maulik PK, Murthy GVS, Walker MF, Pandian JD. Family-led rehabilitation after stroke in India: A Randomised Controlled Trial. *Lancet* 2017; Published online June 27, 2017.
2. Walker MF, Hoffmann TC, Brady MC, Dean CM, Eng JJ, Farrin AJ, Felix C, Forster A, Langhorne P, Lynch EA, Radford KA, Sunnerhagen KS, Watkins CL. Improving the development, monitoring and reporting of stroke rehabilitation research: consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable (SRRR). *International Journal of Stroke* 2017; Vol. 12(5) 472–479.
3. Sprigg N, O'Connor R, Woodhouse L, Krishnan K, England TJ, Connell LA, Walker MF, Bath PM. Granulocyte Colony Stimulating Factor and Physiotherapy after Stroke: Results of a Feasibility Randomised Controlled Trial: Stem Cell Trial of Recovery EnhanceMent after Stroke-3 (STEMS-3 ISRCTN16714730). *PLoS ONE* 2016. 11(9): e0161359. doi:10.1371/journal.pone.0161359 Received: February 4, 2016, Accepted: August 4, 2016, Published: September 9, 2016
4. Clarke CE, Patel S, Ives N, Rick CE, Dowling F, Woolley R, Wheatley K, Walker MF, Sackley CM; PD REHAB Collaborative Group. Physiotherapy and Occupational Therapy vs No Therapy in Mild to Moderate Parkinson Disease: A Randomized Clinical Trial. *JAMA Neurol.* 2016; 73(3):291-9. ISRCTN17452402. DOI: 10.1001/jamaneurol.2015.4452 Published online 19 January 2016, Published March 2016
5. Sackley CM, Walker MF, Burton CR, Watkins CL, Mant J; Roalfe AK, Wheatley K, Sheehan B, Sharp L, Stant KE, Fletcher-Smith JC, Steel K, Wilde K, Irvine L, Peryer G, on behalf of the OTCH trial investigators. An occupational therapy intervention for residents with stroke related disabilities in UK care homes (OTCH): cluster randomised controlled trial. *British Medical Journal* 2015; 350(246), 1-11

s47F



Perispinal Etanercept Clinical Trial Grant Application Form

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

Perispinal Etanercept Clinical Trial Grant Application Form

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

S47F

This document has been released under
 the Freedom of Information Act 1982
 by the Department of Health, Disability and Ageing

Top 5 Publications

1. Bath PM, Woodhouse L, Scutt P, Krishnan K, Wardlaw JM, Bereczki D, Sprigg N, Berge E, Beridze M, Caso V, Chen C, Christensen H, Collins R, El Etribi A, Laska AC, Lees KR, Ozturk S, Phillips S, Pocock S, de Silva HA, Szatmari S, Utton S; for ENOS Trial Investigators. Efficacy of nitric oxide, with or without continuing antihypertensive treatment, for management of high blood pressure in acute stroke (ENOS): a partial-factorial randomised controlled trial. *Lancet*. 2015 Feb 14;385(9968):617-28. doi: 10.1016/S0140-6736(14)61121-1. Epub 2014 Oct 21. Erratum in: *Lancet*. 2015 Feb 14;385(9968):606.
2. Kalladka D, Sinden J, Pollock K, Haig C, McLean J, Smith W, McConnachie A, Santosh C, Bath PM, Dunn L, Muir KW. Human neural stem cells in patients with chronic ischaemic stroke (PISCES): a phase 1, first-in-man study. *Lancet* 2016 Aug 20;388(10046):787-96. doi: 10.1016/S0140-6736(16)30513-X. Epub 2016 Aug 3.
3. Bath PM, Woodhouse LJ, Appleton JP, Beridze M, Christensen H, Dineen RA, Duley L, England TJ, Flaherty K, Havard D, Heptinstall S, James M, Krishnan K, Markus HS, Montgomery AA, Pocock SJ, Randall M, Ranta A, Robinson TG, Scutt P, Venables GS, Sprigg N; TARDIS Investigators. Antiplatelet therapy with aspirin, clopidogrel, and dipyridamole versus clopidogrel alone or aspirin and dipyridamole in patients with acute cerebral ischaemia (TARDIS): a randomised, open-label, phase 3 superiority trial. *Lancet*. 2017 Dec 20.

Perispinal Etanercept Clinical Trial Grant Application Form

4. Sprigg N, Flaherty K, Appleton JP, Al-Shahi Salman R, Bereczki D, Beridze M, Christensen H, Ciccone A, Collins R, Czlonkowska A, Dineen RA, Duley L, Egea-Guerrero JJ, England TJ, Krishnan K, Laska AC, Law ZK, Ozturk S, Pocock SJ, Roberts I, Robinson TG, Roffe C, Seiffge D, Scutt P, Thanabalan J, Werring D, Whyne D, **Bath PM**; TICH-2 Investigators. Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage (TICH-2): an international randomised, placebo-controlled, phase 3 superiority trial. *Lancet* 2018 May 26;391(10135):2107-2115. doi: 10.1016/S0140-6736(18)31033-X.
5. Dzewas R, Stellato R, van der Tweel I, Walther E, Werner CJ, Braun T, Citerio G, Jandl M, Friedrichs M, Nötzel K, Vosko MR, Mistry S, Hamdy S, McGowan S, Warnecke T, Zwittag P, Bath PM, on behalf of the PHAST-TRAC Investigators. PHaryngeal electrical STimulation for early decannulation in TRACheotomised stroke patients with neurogenic dysphagia (PHAST-TRAC): a prospective randomised single-blinded trial. *Lancet Neurology* 2018; 17; 849-59.

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

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.



Perispinal Etanercept Clinical Trial Grant Application Form

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)

S47F

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing



Perispinal Etanercept Clinical Trial Grant Application Form

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing



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 \$47(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 \$47(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)		
	2019	2020	2021
<i>Please add a new line for each item requested.</i>			
Ethics: submission	<div style="font-size: 48px; font-weight: bold; opacity: 0.5;"> This document has been released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing </div> <div style="font-size: 100px; font-weight: bold; opacity: 0.8;"> \$47(1)(b) </div>		
Clinical Trial Notification			
Grant endorsement ASTN			
CRF Redcap programming & randomisation			
Tables for injection			
Site Start-Up fee			
Pharmacy allowance			
Project coordinator & monitoring PSP4			
Statistics & analytic support			
Drug costs 25 mg etanercept			
Drug costs placebo			
Screening costs: lab			
Lab set up and approval			
Travel costs to Florida to learn injection technique			
Per patient cost			
Patient travel cost & parking			
Submission to data sharing platform Vivli (USD 47(1)(b))			
Archiving site fee			



Perispinal Etanercept Clinical Trial Grant Application Form

	2019 Total	2020	2021
	s47(1)(b)		

2019-2021 Project Budget Total:	s47(1)(b)
--	------------------

4.2. Justification of each budget item

Personnel:

Direct Research Costs:

Equipment:

Personnel: An experienced project coordinator (NHMRC PSP level 4, annual rate \$s47(1)(b)) will be appointed to coordinate and manage the trial and perform site data monitoring. This is a full-time position over the entire course of the grant. In kind support will be provided by steering committee and DSMB.

Equipment: 4 Trendelenburg tables (listed cost of \$s47(1)(b)) will be acquired to position the patient appropriately after injection, for each of the enrolling sites

Direct research costs:

Ethics submission: \$s47(1)(b) per site

ASTN endorsement: \$s47(1)(b)

Clinical trial notification: \$s47(1)(b) per site

CRF Redcap programming and randomization support: an electronic CRF will be constructed including a randomization module at a cost of \$s47(1)(b) including maintenance and hosting

Statistics and analytics support: \$s47(1)(b) over 2.5 years (includes safety reporting & analysis, preparing DSMB analysis, statistical support for publication)

Pharmacy allowance: pharmacist support including preparation, blinding, shipping and handling of IP \$s47(1)(b)

Site start-up fee: includes trial coordinator time in preparing and submission for research governance, site initiation, adaptation of PICF, screening of historic patient list \$s47(1)(b) per site

Etanercept and placebo: s47(1)(b) per injection of etanercept and s47(1)(b) per injection of placebo (includes injection material), 255 injections of etanercept and 85 placebo injections

Screening lab: screening for TBC, hepatitis B and C as required before administration of IP @ s47(1)(b) per screening test for estimated 200 patients (assuming 30 screen failures)

Per patient cost: 4 visits per patient @ \$s47(1)(b) includes stroke physician or neurologist time, assessor time, trial coordinator time (data entry, time with monitor, resolving queries)

Patient travel cost & parking: travel to and from study site including parking costs (\$s47(1)(b) per patient)



Perispinal Etanercept Clinical Trial Grant Application Form

Archiving: trial documents need be archived for minimum periods of time after trial completion
@\$^{s47(1)(b)} per site

Open data sharing hosting: Vivli data sharing platform (www.vivli.org), provides solution for open data sharing, curating and independent review panel (US\$^{s47(1)(b)})

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

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:

1. Fernbach C. Brain injury treatment Etanercept in line for trials, legalisation after push by Queensland families. Retrieved from: <https://www.abc.net.au/news/2017-06-13/brain-injury-treatment-etanercept-trials-legalisation/8610112>. Accessed on 19/11/2018
2. Weaver M. Andrew Marr to undergo 'controversial' US stroke treatment. Retrieved from: <https://www.theguardian.com/media/2016/dec/08/andrew-marr-to-undergo-controversial-us-stroke-treatment>. Accessed on 19/11/2018
3. Tobinick E, Kim NM, Reyzin G, Rodriguez-Romanacce H, DePuy V. Selective TNF inhibition for chronic stroke and traumatic brain injury: an observational study involving 629 consecutive patients treated with perispinal etanercept. *CNS Drugs*. 2012;26:1051-1070
4. Tobinick E. Rapid improvement of chronic stroke deficits after perispinal etanercept: three consecutive cases. *CNS Drugs*. 2011;25:145-155
5. Tobinick EL. Targeted etanercept for treatment-refractory pain due to bone metastasis: two case reports. *Clin Ther*. 2003;25:2279-2288
6. Tobinick EL. Targeted etanercept for discogenic neck pain: uncontrolled, open-label results in two adults. *Clin Ther*. 2003;25:1211-1218
7. Tobinick EL, Britschgi-Davoodifar S. Perispinal TNF-alpha inhibition for discogenic pain. *Swiss Med Wkly*. 2003;133:170-177
8. Tobinick EL, Gross H. Rapid improvement in verbal fluency and aphasia following perispinal etanercept in Alzheimer's disease. *BMC Neurol*. 2008;8:27
9. Tobinick EL, Gross H. Rapid cognitive improvement in Alzheimer's disease following perispinal etanercept administration. *J Neuroinflammation*. 2008;5:2
10. Novella S. Enbrel for Stroke and Alzheimer's. Retrieved from: <https://sciencebasedmedicine.org/enbrel-for-stroke-and-alzheimers/>. Accessed on 19/11/2018
11. Pardridge WM. The blood-brain barrier: bottleneck in brain drug development. *NeuroRx*. 2005;2:3-14
12. Boado RJ, Hui EK, Lu JZ, Zhou QH, Pardridge WM. Selective targeting of a TNFR decoy receptor pharmaceutical to the primate brain as a receptor-specific IgG fusion protein. *J Biotechnol*. 2010;146:84-91
13. Tobinick EL. Perispinal Delivery of CNS Drugs. *CNS Drugs*. 2016;30:469-480
14. Roerink ME, Groen RJ, Franssen G, Lemmers-van de Weem B, Boerman OC, van der Meer JW. Central delivery of iodine-125-labeled cetuximab, etanercept and anakinra after perispinal injection in rats: possible implications for treating Alzheimer's disease. *Alzheimers Res Ther*. 2015;7:70
15. Butchart J, Brook L, Hopkins V, Teeling J, Puntener U, Culliford D, et al. Etanercept in Alzheimer disease: A randomized, placebo-controlled, double-blind, phase 2 trial. *Neurology*. 2015;84:2161-2168
16. Gronseth GS, Messe SR. Practice advisory: Etanercept for poststroke disability: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86:2208-2211
17. TGA. Etanercept Product Insert. Retrieved from: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=etanercept>. Accessed on 21/11/2018
18. Leombruno JP, Einarson TR, Keystone EC. The safety of anti-tumour necrosis factor treatments in rheumatoid arthritis: meta and exposure-adjusted pooled analyses of serious adverse events. *Ann Rheum Dis*. 2009;68:1136-1145



Perispinal Etanercept Clinical Trial Grant Application Form

19. Bernhardt J, Hayward KS, Kwakkel G, Ward NS, Wolf SL, Borschmann K, 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
20. Kwakkel G, Lannin NA, Borschmann K, English C, Ali M, Churilov L, et al. Standardized Measurement of Sensorimotor Recovery in Stroke Trials: Consensus-Based Core Recommendations from the Stroke Recovery and Rehabilitation Roundtable. *Neurorehabil Neural Repair*. 2017;31:784-792
21. Quinn TJ, Langhorne P, Stott DJ. Barthel index for stroke trials: development, properties, and application. *Stroke*. 2011;42:1146-1151
22. Harrison JK, McArthur KS, Quinn TJ. Assessment scales in stroke: clinimetric and clinical considerations. *Clin Interv Aging*. 2013;8:201-211
23. Reeves M, Lisabeth L, Williams L, Katzan I, Kapral M, Deutsch A, et al. Patient-Reported Outcome Measures (PROMs) for Acute Stroke: Rationale, Methods and Future Directions. *Stroke*. 2018;49:1549-1556
24. Anderson C, Laubscher S, Burns R. Validation of the Short Form 36 (SF-36) health survey questionnaire among stroke patients. *Stroke*. 1996;27:1812-1816
25. Wyrwich KW, Tierney WM, Babu AN, Kroenke K, Wolinsky FD. A comparison of clinically important differences in health-related quality of life for patients with chronic lung disease, asthma, or heart disease. *Health Serv Res*. 2005;40:577-591
26. Bivard A, Lillicrap T, Krishnamurthy V, Holliday E, Attia J, Pagram H, et al. MIDAS (Modafinil in Debilitating Fatigue After Stroke): A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Trial. *Stroke*. 2017;48:1293-1298

This document has been released under
the Freedom of Information Act 1992
by the Department of Health, Disability and Ageing



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
Vincent Thijs	s47F	27/11/2018

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 Director (please print)	Signature of Director	Date
s47F		28/11/2018

 Outlook

RE: EPCD 19 - National Stroke Foundation Query Variation and Report [SEC=OFFICIAL]

From s22 @Health.gov.au>
Date Fri 10/28/2022 9:56 AM
To Accelerated Research Program <arp@industry.gov.au>; s22 @health.gov.au>
Cc s22 @health.gov.au>; s22 @industry.gov.au>

Good morning s22

Thank you for liaising with the grantee for this info.

In regards to their ad-hoc progress report that was submitted with the variation package, this has been assessed and is currently with the Delegate for approval.

Cheers,

s22

From: Accelerated Research Program <arp@industry.gov.au>
Sent: Thursday, 27 October 2022 11:27 AM
To: s22 @health.gov.au>; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @industry.gov.au>
Subject: RE: EPCD 19 - National Stroke Foundation Query Variation and Report [SEC=OFFICIAL]

Hi s22

The grantee has provided the following response to your request for further information

- How researchers for the PESTO trial intend to disseminate their research findings for the PESTO trial?
The team will use their extensive national and international networks to disseminate their research findings. The results will be presented at an international conference, probably the prestigious International Stroke Conference in 2024. The researchers aim to publish the result in a top tier journal such as the Lancet Neurology or JAMA as their findings will have worldwide impacts. With the help of The Florey Institute of Neuroscience and Mental Health and Stroke Foundation, a press release will be disseminated at the time of the presentation of the findings. Additionally, the researchers aim to present their findings to the trial's participants. Finally, the team will use the Stroke Foundation's platforms to communicate the findings to the wider stroke community in Australia and work to incorporate the findings into clinical guidelines.

- Methods for translation of the findings into practice.

Dependent on the findings, the trial's results may impact clinical guidelines if no clear effect of the treatment will be found as this will provide the first large scale evidence of absence of effect. If this is the case, the team will work with Stroke Foundation to adapt guidelines. If promising signals are found, the team will apply to funders to perform a phase III trial to confirm the findings and discuss with the TGA on a pathway to obtain registration of the investigational product for a stroke indication. Moreover, the team will have to discuss with the patent holder and IP lawyers to administer this product without infringing patent law. Conducting a larger scale trial will require development of a training program to train health professionals to administer the intervention.

Please let me know if you require anything further

Kind Regards

s22

From: s22 @health.gov.au
Sent: Tuesday, 25 October 2022 10:21 AM
To: Accelerated Research Program <arp@industry.gov.au>
Cc: s22 @health.gov.au; s22 @Health.gov.au; s22 @industry.gov.au
Subject: RE: EPCD 19 - National Stroke Foundation Query Variation and Report [SEC=OFFICIAL]

Hi s22

Thanks for sending us the signed variation contract. I'll send this to our delegate today. I was waiting to talk to s22 last week about the ad-hoc report so let me get back to you on this one.

Will be in touch soon.

s22

From: Accelerated Research Program <arp@industry.gov.au>
Sent: Tuesday, 25 October 2022 8:11 AM
To: s22 @health.gov.au; Accelerated Research Program <arp@industry.gov.au>
Cc: s22 @health.gov.au; s22 @Health.gov.au; s22 @industry.gov.au
Subject: EPCD 19 - National Stroke Foundation Query Variation and Report [SEC=OFFICIAL]

Hi s22

There are a few things going on with this project at the moment:

1. Please find attached the signed variation contract for countersigning by the Delegate.
2. I have requested the information from the grantee as per your email below. I have requested the information by Friday as I will be on leave Monday 31st October and Tuesday 1st November (as will many Melbournians I suspect)
3. The Ad Hoc report that was requested as part of the conditional approval of the Stroke Foundation's last progress report was provided as an attachment to the variation request documentation. Do you require us to complete a checklist for this or are you able to just approve it based on the fact that the variation has been approved? I won't be able to update the system with the executed agreement until I approve this report.

Thanks

s22

OFFICIAL

From: s22 @health.gov.au
Sent: Friday, 21 October 2022 6:04 PM
To: Accelerated Research Program <arp@industry.gov.au>
Cc: s22 @health.gov.au; s22 @Health.gov.au; s22 @industry.gov.au; s22 @industry.gov.au
Subject: EPCD 19 - National Stroke Foundation - query [SEC=OFFICIAL]

Hi s22 and Team,

We have received an enquiry about how research findings will be disseminated for one of the projects - *Return to Life PESTO (Perispinal Etanercept to improve Stroke Outcomes)* which forms as part of the National Stroke Foundation grant.

Could you please request from the grantee to provide information which outlines:

- How researchers for the PESTO trial intend to disseminate their research findings for the PESTO trial (note this information was provided to us for the Return to Work project as part of their annual progress report).
- Methods for translation of their findings into practice.

We greatly appreciate if you could ask the grantee to provide us with this information by Monday 31 October 2022.

Happy to discuss,

s22

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

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

This document has been prepared under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

From: s22
Sent: Wednesday, 15 January 2020 9:51 AM
To: s22
Cc: Somi, Masha; s22
Subject: RE: PSE Clinical Trial paper [SEC=OFFICIAL]

Good morning s22

We've managed to get some preliminary information in respect of the matter below. We are seeking additional information, however, I wanted to give you an early update.

In summary, the National Stroke Foundation is progressing the 'return to life, return to work' project using the \$1m announced by the Minister on [6 October 2018](#). The project comprises a targeted clinical research investment in stroke recovery for young survivors.

The \$1m has been used to fund two specific clinical trial activities, (1) Perispinal Etanercept to Improve Stroke Outcomes or PESTO; and (2) a study into embedded vocational rehabilitation intervention to improve employment outcomes.

The PESTO activity was awarded to Professor Vincent Thijs, Florey Institute of Neuroscience and Mental Health by the National Stroke Foundation following a competitive call for applications. The project value is s47(1)(b) The remaining s22 was allocated to the second activity detailed above.

The most recent progress report from the National Stroke Foundation submitted last year indicated that protocol for the PESTO activity was being finalised and that enrolment was expected to commence in the last quarter of the 2019 calendar year.

We have contacted the National Stroke Foundation for a status update on the PESTO activity. I'll inform you of current status once received.

Regards

s22

A/g CEO
 Health and Medical Research Office
 Health Economics and Research Division
 Department of Health
 T: (02) 6289s22 [@health.gov.au](mailto:s22@health.gov.au)

PO Box 9848, Canberra ACT 2601, Australia

From: s22
Sent: Tuesday, 14 January 2020 4:12 PM
To: s22 [@health.gov.au](mailto:s22@health.gov.au)
Cc: Somi, Masha <Masha.Somi@health.gov.au>; s22 [@health.gov.au](mailto:s22@health.gov.au)
Subject: FW: PSE Clinical Trial paper [SEC=OFFICIAL]

Hi s22

I have asked the team to investigate as a priority, but I'm unable to guarantee provision of helpful advice this afternoon. We need to identify the original grant support referred to below for background and context, which appears to be early on in the establishment of MRFF.

Regards

s22

A/g CEO
 Health and Medical Research Office
 Health Economics and Research Division
 Department of Health
 T: (02) 6289 s22 @health.gov.au

PO Box 9848, Canberra ACT 2601, Australia

From: s22 @health.gov.au>
Sent: Tuesday, 14 January 2020 3:38 PM
To: s22 @health.gov.au>
Cc: Somi, Masha <Masha.Somi@health.gov.au>
Subject: FW: PSE Clinical Trial paper [SEC=OFFICIAL]

Hi s22

Can I please have some urgent advice this afternoon?

Thanks

s22

From: s47F @usq.edu.au>
Sent: Tuesday, 14 January 2020 2:38 PM
To: s22 @pm.gov.au>
Subject: PSE Clinical Trial paper

Good afternoon s22

I know you are likely to be incredibly busy with all of the bushfire response but wanted to email you a copy of the paper that was published last week from the Griffith University School of Medical Science Perispinal Etanercept Treatment (PSE) for Stroke patients.

The attached publication shows that PSE is an effective treatment for reducing both neuropathic pain and muscle spasticity in the affected shoulder and also provides strong evidence that Etanercept injected perispinally reaches the brain and warrants further research.

We were grateful for your support when you were working with Minister Greg Hunt, but unfortunately the \$1M allocated via the National Stroke Foundation has not resulted in a clinical trial at this stage. Given that they were clear that they were not prepared to consider contributing any of the \$1M allocated to the existing Griffith University PSE trial, and did not consider our application for being an additional research site on the Return to Life, Return to Work Clinical Trial (even though our team included s47F –inventor of the treatment & Professor s47F the Chief Scientific Investigator on the only PSE clinical trial) many would question if this is the best use of tax-payers money. As we have some significant media around this ground breaking publication, the non-expenditure of this \$1M is likely to be justifiably raised as a concern.

I would be grateful if you could pass this on to Minister Greg Hunt's team who should be interested in the new publication and the potential for its help for those affected by stroke. It certainly highlights the need for our government to fund research that gets completed and alleviates suffering.

Please feel free to contact me should you require any additional information about this ground-breaking research.

Regards s47F

s47F

s47F

School of Nursing and Midwifery
Faculty of Health, Engineering & Sciences
University of Southern Queensland
Toowoomba 4350
AUSTRALIA
Phone s47F

This email (including any attached files) is confidential and is for the intended recipient(s) only. If you received this email by mistake, please, as a courtesy, tell the sender, then delete this email.

The views and opinions are the originator's and do not necessarily reflect those of the University of Southern Queensland. Although all reasonable precautions were taken to ensure that this email contained no viruses at the time it was sent we accept no liability for any losses arising from its receipt.

The University of Southern Queensland is a registered provider of education with the Australian Government.
(CRICOS Institution Code QLD 00244B / NSW 02225M, TEQSA PRV12081)

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

From: s47F [redacted]@strokefoundation.org.au>
Sent: Thursday, 30 January 2020 4:04 PM
To: Accelerated Research Program
Cc: Research; s22 [redacted]
Subject: National Stroke Foundation Progress Report Jan 2020 - Accelerated Research with attachments v2.pdf [SEC=No Protective Marking]
Attachments: National Stroke Foundation Progress Report Jan 2020 - Accelerated Research with attachments v2.pdf; ATT00001.htm

Afternoon,

Please see attached Stroke Foundation report.

This version supersedes the document provided earlier today - apologies.

For more information please contact s47F [redacted] or s47F [redacted]@strokefoundation.org.au.

Again, apologies for any confusion.

Thanks

s47F [redacted]

National Manager, Public Affairs & Advocacy

Stroke Foundation

Level 7, 461 Bourke St, Melbourne VIC 3000

D 03 s47F [redacted]

StrokeLine: 1800 STROKE (1800 787 653)

s47F [redacted] [@strokefoundation.org.au](mailto:s47F@strokefoundation.org.au)



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

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

This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing