

s22

From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Sent: Wednesday, 17 July 2024 6:21 AM
To: s22 ; Natalie Eaton-Fitch
Cc: s47F ; s22 ; s22 ; CARLILE, Chris
Subject: RE: FOR CLEARANCE RE: NCNED Developments [SEC=OFFICIAL]-reply #3

Dear s22 and colleagues,

Further to our previous email I am delighted to inform an independent research team from Germany evaluated our TRPM3 research for the underlying pathology of ME/CFS and Long COVID with potential application for LDN as a treatment and concluded a) TRPM3 as the underlying of the pathology of ME/CFS and LC and 2) LDN may be an effective treatment intervention for ME/CFS and LC.

This is wonderful news for us as this is all our work in ME/CFS and Long COVID where it proves our research findings are correct for the identification of the pathology of ME/CFS and Long COVID as well as potential treatments. We count not be more thrilled with this publication and firmly cements our international position the world leaders in pathomechanism/treatment ME/CFS and long COVID. In addition, notable international clinical/research institutes have been contacting us to undertake work with them.

Link: [Potential pathophysiological role of the ion channel TRPM3 in myalgic encephalomyelitis/chronic fatigue syndrome \(ME/CFS\) and the therapeutic effect of low-dose naltrexone - PMC \(nih.gov\)](#)

Finally, our research in illness presentation in ME/CFS and Long COVID patients has also been published and also presented at the International Public Health Conference. We continue to be the first in the world and nationally to report these findings too.

Link: [Illness presentation and quality of life in myalgic encephalomyelitis/chronic fatigue syndrome and post COVID-19 condition: a pilot Australian cross-sectional study - PubMed \(nih.gov\)](#)

Best wishes and take care.

Sonya

Dr Sonya Marshall-Gradisnik
Inaugural Stafford Fox Medical Research Foundation Professorial Research Fellowship

Professor Immunology

Director: National Centre for Neuroimmunology and Emerging Diseases

Griffith University | Gold Coast Campus | QLD 4111 | s47F

T +61 7 5678 0725 | E s.marshall-gradisnik@griffith.edu.au

From: Sonya Marshall-Gradisnik
Sent: Tuesday, April 30, 2024 8:27 AM
To: s22 ; Natalie Eaton-Fitch
Cc: s47F ; s22 ; CARLILE, Chris
Subject: RE: FOR CLEARANCE RE: NCNED Developments [SEC=OFFICIAL]-reply

Dear s22 and colleagues,

Thank you for your email and e-introduction to s22

We look forward to receiving the communique and thank you for including our Best Practice Guidelines for [Myalgic Encephalomyelitis/Chronic Fatigue Syndrome](#).

Re The National Academies of Science Engineering and Medicine (U.S.A.) link or source: We are yet to receive the link or the document. It is our understanding this link will be provided in the coming two months. As soon as Natalie and I receive this information we will send it to you. If we are able to assist with new Clinical Guidelines for ME/CFS or provide further direction for PASC we would welcome these opportunities to collaborate with you and your team.

The embargo for our latest research findings will be removed this Thursday. ABC National interviewed us yesterday where we anticipated our world first research will be promulgated Thursday/Friday.

Natalie and I will continue to appraise you of our achievements and research/external invitations seeking our expertise.

Best wishes and I hope you have a great week.

Sonya

Dr Sonya Marshall-Gradisnik
Inaugural Stafford Fox Medical Research Foundation Professorial Research Fellowship

Professor Immunology

Director: National Centre for Neuroimmunology and Emerging Diseases

Griffith University | Gold Coast Campus | QLD 4111 | s47F

T +61 7 5678 0725 | E s.marshall-gradisnik@griffith.edu.au

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

Sent: Friday, April 26, 2024 6:19 PM

To: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>; Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>

Cc: s47F <[\[REDACTED\]@griffith.edu.au](mailto:[REDACTED]@griffith.edu.au)>; s22 <[REDACTED]>

<[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>; s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; CARLILE, Chris <s22@health.gov.au>

Subject: RE: FOR CLEARANCE RE: NCNED Developments [SEC=OFFICIAL]

Dear Sonya and colleagues.

Thank you for keeping us updated on your interesting research work. Please do keep us updated with any publication details.

My team is preparing a communique to go out through the various departmental Primary Care newsletters about available resources/publications (Australian and International) for the clinical management of symptoms for post-infection on set conditions such as PASC and ME/CFS, amongst others. We are hoping to have a communique ready in mid-late May, and will be including the Best Practice Guidelines for [Myalgic Encephalomyelitis/Chronic Fatigue Syndrome](#) that you and Natalie were involved with. I was wondering if there is a URL/website for the National Academies of Science Engineering and Medicine (U.S.A.) paper that Natalie mentioned in her previous email?

Lastly, I'd like to e-introduce you to s22 <[REDACTED]>, who has joined my team last week. s22 <[REDACTED]> team has responsibility for a range of post infection onset conditions, including ME/CFS & PASC, as well as a number of other chronic conditions. s22 <[REDACTED]> is a registered nurse with a strong background in Chronic Condition management, and most recently worked in the Chronic Conditions technical advisory team in the National Disability Insurance Agency (NDIA). s22 <[REDACTED]> is still in my team, but working on other chronic conditions now.

With best regards,

s22 <[REDACTED]>

From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Sent: Monday, April 22, 2024 12:01 PM
To: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>; s22 [REDACTED] <[REDACTED]@health.gov.au>;
 CARLILE, Chris s22 [REDACTED] <[REDACTED]@health.gov.au>
Cc: s47F [REDACTED] <[REDACTED]@griffith.edu.au>; s22 [REDACTED] <[REDACTED]@health.gov.au>;
 s22 [REDACTED] <[REDACTED]@health.gov.au>
Subject: RE: FOR CLEARANCE RE: NCNED Developments

Dear Chris, s22 [REDACTED] and team,

Further to Natlie's email we are delighted to provide you with further achievements:

1. Early next week there will be a press release re NCNED latest long COVID research findings. The research is embargoed at the moment, however, we provide this **confidential information** so you are abreast of our work:

Confidential:

Investigation into the restoration of TRPM3 ion channel activity in post-COVID-19 condition: a potential pharmacotherapeutic target.

Etianne Martini Sasso, Katsuhiko Muraki, Natalie Eaton-Fitch, Peter Smith, Andrew Jeremijenko, Paul Griffin and Sonya Marshall-Gradisnik.

Frontiers in Immunology. Accepted.

2. Dr Eaton-Fitch and I were invited by Australian Doctor- largest Australian GP Communication Journal- to write an article on the management and potential treatment of ME/CFS and long COVID. This paper is nearing the final stages of publication where we will send this to you upon publication.

3. NCNED has just published a research paper that is the first in the world to report neurochemical changes in ME and Long COVID patients are the same. This novel study revealed level of neurochemicals in the brain were associated with symptoms like cognitive impairment, unrefreshing sleep, and physical limitation in long COVID and ME/CFS patients. This finding suggests these neurochemicals may play a key role in the development and progression of these conditions. Finally, this research was undertaken using 7 Tesla MRI and aligns to the laboratory gold standard findings we are reporting on ion channels (ie TRPM3). The paper was published in the American Journal of Medicine.

Link: [https://www.amjmed.com/art.../S0002-9343\(24\)00216-X/fulltext](https://www.amjmed.com/art.../S0002-9343(24)00216-X/fulltext)

4. NCNED published two weeks ago a research paper that is again the first in the world to report **significant reductions in the functional connectivity between the brainstem and cerebellum regions of ME/CFS patients** compared with healthy controls. The brainstem and cerebellum are involved in the motor, cognitive and autonomic functions, providing rationale for the clinical symptoms, such as cognitive and physical impairment reported by ME/CFS patients. Functional connectivity analysis using ultra-high-field MRI is a promising technique for reliably deciphering the underlying pathomechanisms involved in the origin and progression of ME/CFS.

The paper was published in Frontiers in Neuroscience.

Link:

https://www.frontiersin.org/articles/10.3389/fnins.2023.1318094/full?utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Neuroscience&id=1318094

5.. NCNED has been successful for funding from the United Kingdom. NCNED researchers have been successfully been awarded an ME Research UK grant for \$438,000 to track the progression of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Long COVID. The study will use an ultra-high

field 7 Tesla (7T) MRI to capture a clearer depiction of brain regions and detect subtle brain changes in ME/CFS and Long COVID patients.

6. NCNED will commence the first national Long COVID clinical trial on May 20, 2024. This clinical trial is the first CT in Australia for long COVID patients and is underpinned by our world first results for Long COVID we have published since 2021. This funding has been provided by Mineral Resources, WA.

Best wishes

Sonya

Dr Sonya Marshall-Gradisnik
Inaugural Stafford Fox Medical Research Foundation Professorial Research Fellowship

Professor Immunology
Director: National Centre for Neuroimmunology and Emerging Diseases
Griffith University | Gold Coast Campus | QLD 4111 | s47F
T +61 7 5678 0725 | E s.marshall-gradisnik@griffith.edu.au

From: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>
Sent: Tuesday, March 5, 2024 4:11 PM
To: s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; CARLILE, Chris <s22 <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>
Cc: s47F <[\[REDACTED\]@griffith.edu.au](mailto:[REDACTED]@griffith.edu.au)>; s22 <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>;
s22 <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Subject: RE: FOR CLEARANCE RE: Feedback on ME/CFS guideline proposal from NCNED following meeting Thursday 2nd November [SEC=OFFICIAL]

Dear Dr s22 <[REDACTED]> Mr Carlile and team,

I hope this email finds you all well.

We are writing to notify you of the release of Best Practice Guidelines for [Myalgic Encephalomyelitis/Chronic Fatigue Syndrome](#) published in BMJ (U.K.). These guidelines were a collaborative effort by Sonya and myself with Professor James Baraniuk who is internationally known for his efforts in ME/CFS. To best align with new research and the evolving understanding of ME/CFS, we endorsed the removal of treatments and management protocols that are at risk of causing harm, such as graded exercise therapy (GET) which is currently incorporated within the Australian guidelines for ME/CFS. The contribution of NCNED researchers in the mentioned BMJ Guidelines was well-received by Australians living with ME/CFS.

When we met in early November, we also discussed that Sonya and myself were involved in the writing of guidelines and recommendations of Long COVID for National Academies of Science Engineering and Medicine, U.S.A. Our contribution has been accepted for publication following review and will be published in the coming weeks. We will ensure this documented is forwarded once available.

We anticipate the results of the 2024/2025 budget, particularly in relation to potential funding allocated for the development of new Australian guidelines for ME/CFS.

If you have any questions regarding the guidelines above, please let us know.

We look forward to hearing from you and appreciate your time.

Kind Regards,

Natalie Eaton-Fitch, PhD

Research Fellow | pronouns: she/her

National Centre for Neuroimmunology and Emerging Diseases (NCNED)

Consortium Health International for ME (CHIME)

MENZIES Health Institute Queensland

Griffith University | Gold Coast | s47F

P +617 567 89282 | M +s47F | E n.eaton-fitch@griffith.edu.au

I choose to work & send emails outside normal office hours. There is no expectation to respond to my email outside of your work hours.



Griffith University acknowledges the people who are the traditional custodians of the land and pays respect to the Elders, past and present, and extends that respect to all Aboriginal and Torres Strait Islander peoples.

Gold Coast campus is situated on the land of the Yugambah/Kombumerri peoples.

From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>

Sent: Friday, December 1, 2023 6:03 AM

To: s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>

Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>; s47F <[REDACTED]> <[\[REDACTED\]@griffith.edu.au](mailto:[REDACTED]@griffith.edu.au)>; CARLILE, Chris <[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)>; Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>

Subject: RE: FOR CLEARANCE RE: Feedback on ME/CFS guideline proposal from NCNED following meeting Thursday 2nd November [SEC=OFFICIAL]

Dear s22

I hope this email finds you well.

Your timing could not be more perfect. Thank you.

We are currently refining this document and anticipate submitting it on December 19.

We will advise you when we have lodged the submission.

Best wishes and take care.

Sonya

Dr Sonya Marshall-Gradisnik

Professor of Immunology

Griffith University

Menzies Health Institute Queensland

Director National Centre for Neuroimmunology and Emerging Diseases

s47F

Parklands QLD, 4222

Telephone: 07 5678 0725

s47F

Email: s.marshall-gradisnik@griffith.edu.au**From:** s22 @health.gov.au>**Sent:** Friday, December 1, 2023 5:50 AM**To:** Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>**Cc:** Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>; s47F @griffith.edu.au>; CARLILE, Chris <s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>**Subject:** FW: FOR CLEARANCE RE: Feedback on ME/CFS guideline proposal from NCNED following meeting Thursday 2nd November [SEC=OFFICIAL]

Dear Sonya and team

Thanks again for meeting with us to discuss your proposal for the development of clinical practice guidelines for ME/CFS a few weeks ago. I hope the conference went well on 9-10 November.

As mentioned during our meeting, consideration around funding for activities such as the development of ME/CFS guidelines is generally determined through the budget process. It is anticipated that the Treasury will open a page on its website in December and make a call for proposals to be considered as part of the 2024-25 Budget. Even with this process, there is no certainty of funding for activities within your proposal.

Below we have provided some feedback on the proposal you shared with us that may assist you in refining your pre-budget submission to Treasury:

- Consider/outline how your proposal aligns with relevant frameworks and strategies such as the National Strategic Framework for Chronic Conditions to show the proposal aligns with government policy.
- Provide a few costing options e.g. – low cost proposal (eg. develop guidelines only), medium and high cost options (eg. additional time for maintenance and implementation) and include justifications of each approach. This could also include differing timeframes - what could you do with 1, 2, or 3 years of funding (report financial years not calendar years). The detailed budget breakdown you have provided in your proposal is a good example of the detail required for the funding breakdown for each option but should be presented in financial years. Also, explain why one option is recommended over the others.
- Its pleasing to see that you have considered activities that translate information for consumers and the development of education for health professionals to support implementation of guidelines, but it would also be helpful for you to outline plans for future management of guidelines beyond funding being requested to develop and implement them. For example, are there plans to review the guidelines in future? Who would maintain the guidelines?

I hope this information is of assistance as you refine your proposal.

With best regards,

s22

Dr. s22 (Her/She)

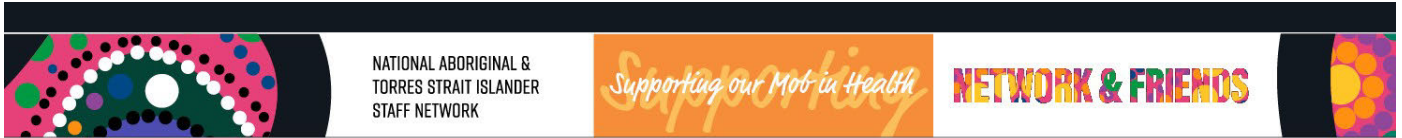
Director – Chronic Conditions – Projects

Cancer, Hearing and Chronic Conditions Division | Hearing Services and Chronic Conditions Branch
Primary and Community Care Group | Australian Government Department of Health and Aged Care

T: 02 s22 | M: s22 | E: s22 @health.gov.au
 GPO Box 9848, Canberra ACT 2601, Australia

This email comes to you from Ngambri and Ngunnawal country.
 Location: Sirius 9.S
 PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.



From: s47F @griffith.edu.au>
Sent: Thursday, 2 November 2023 7:54 AM
To: CARLILE, Chris s22 @health.gov.au>
Cc: s22 @Health.gov.au>; Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>; Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>
Subject: Brief for meeting with Griffith University, NCNED - 2.45 p.m. Thursday 2nd November

Good morning Mr Carlile

Thank you for the invitation extended to the National Centre for Neuroimmunology and Emerging Diseases (NCNED).

We have pleasure in providing you with our brief in preparation for the meeting.

We are looking forward to meeting with you and appreciate the opportunity to brief you on the expertise of the Centre.

Kind regards

s47F

s47F

*Executive Officer - Disability and Rehabilitation/
 Centre Coordinator, National Centre for Neuroimmunology and Emerging Diseases
 Menzies Health Institute Queensland*

s47F

Gold Coast campus

Griffith University Qld 4222

Hours: 7.00 a.m. - 3.00 p.m.

Telephone: +s47F

Email: s47F @griffith.edu.au

Mantra on Salt Beach, Kingscliff, NSW, Australia

RID RESEARCH,
INNOVATION &
DISCOVERY

ME/CFS & LONG COVID

**INTERNATIONAL
CONFERENCE**

9 – 10 November 2023



<https://app.secure.griffith.edu.au/griffithpay/me-cfs-international-conference-2023-rid-research-innovation-and-discovery.html>

This document has been released under
the Freedom of Information Act 1982
by the Department of Health and Aged Care



Dr Dinesh Palipana
Doctor of Medicine and
Adjunct Research Fellow



From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Sent: Wednesday, 4 October 2023 9:31 AM
To: s22 <[REDACTED]@health.gov.au>
Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>; s22 <[REDACTED]@health.gov.au>; CARLILE, Chris <s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>
Subject: RE: Reply #5 : NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile [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.

Dear s22

Apologies for the delay, we are writing a grant for s22 <[REDACTED]> as well as s22 <[REDACTED]>. We have been collecting data to include in these grants, hence last week was a little hectic.

Dr Eaton-Fitch and myself are able to travel to Canberra any time after 21 October. We would be delighted to meet with yourself and Mr Carlile to outline our proposal utilising and adapting the documents we have produced for overseas agencies as well as the models we have been working with overseas (ie Stakeholder Committees) to deliver the new Australian Clinical Guidelines for the patient groups you listed in your email.

We are looking forward to meeting with you and await s22 <[REDACTED]> notification for a meeting.

Best wishes

Sonya

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Wednesday, 27 September 2023 2:58 PM
To: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>; s22 [redacted] <[redacted]@health.gov.au>; CARLILE, Chris <s22 [redacted]@health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>; s22 [redacted] <[redacted]@health.gov.au>
Subject: FW: Reply #4 : NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile [SEC=OFFICIAL]

Hi Sonya,

Thank you for your email to Chris Carlile. I am currently acting in Chris' position and responding on his behalf.

I appreciate you sharing this information about your important work. Our team would be interested to hear your thoughts about how your work could be adapted or adopted to replace the existing guidelines in Australia, or used to inform the development of new clinical guidance on ME/CFS for the Australian context. We would also be interested to discuss the links/overlap of your ME/CFS clinical, research and management guideline document has with long COVID, Fibromyalgia and Ehlers-Danlos Syndromes.

I have copied s22 [redacted] who will be in touch to organise a meeting. Please advise if you will be in Canberra at some stage in the near future, otherwise a virtual meeting can be organised.

Kind regards, s22 [redacted]

s22 [redacted]

A/g Assistant Secretary, Hearing Services and Chronic Conditions Branch

Cancer, Hearing and Chronic Conditions Division | Primary and Community Care Group

Australian Government Department of Health and Aged Care

T: 02 s22 | M: s22 | E: s22 @health.gov.au

This email comes to you from Ngunawal country

Location: Sirius Building Level 9 South

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.



From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Sent: Tuesday, 19 September 2023 2:52 PM
To: CARLILE, Chris <s22@health.gov.au>
Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>
Subject: RE: Reply #4 : NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile [SEC=OFFICIAL]

Dear Chris,

Further to my previous email, I would like to advise you Dr Eaton-Fitch, Professor Baraniuk (USA) and myself have completed and submitted the British Medical Journal (BMJ) Best Practice Clinical Guidelines for ME/CFS. The Editor has engaged relevant stakeholders/reviewers for final amendments where this important document will be finalised by 25 November, 2023.

In addition, our second clinical document Dr Eaton-Fitch and I were requested by the National Academies for Medicine and Science, USA, has been submitted. It now resides with the Stakeholder Committee (clinicians, researchers and patient advocates) for minor amendments (if any) that will be finalised Feb, 2024. This ME/CFS clinical, research and management guideline document also addresses the overlap with long COVID, Fibromyalgia and Ehlers-Danlos Syndromes. The feedback

from the National Academies has been “we have gone above and beyond the statement of work” for these guidelines.

Given we are recognised as world authorities in this field, and we have successfully completed these important ME/CFS guidelines by international agencies, we seek your guidance how Dr Eaton-Fitch and myself may provide leadership for the new Australian Clinical Guidelines for ME/CFS.

We would welcome a face-to-face meeting to further discuss this initiative and the framework we have used/implemented with stakeholders to ensure the successful outcome of these clinical guideline documents by these overseas agencies.

All my very best and we look forward to your reply to developing these new Australian Clinical Guidelines.

Sonya

From: Sonya Marshall-Gradisnik
Sent: Tuesday, 20 June 2023 9:25 AM
To: CARLILE, Chris s22 [REDACTED] <[REDACTED]@health.gov.au>
Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>
Subject: RE: Reply #3 : NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile [SEC=OFFICIAL]

Dear Chris,

Thank you for not only your prompt response, but also acknowledging the work currently underway at the NCNED.

As discussed it is critical that new Australian ME/CFS clinical guidelines are completed. Given NCNED's expertise and international recognition we seek your direction to submit a proposal to deliver these new and timely ME/CFS Guidelines to improve the lives of 250,000 Australians (plus emerging cases).

The current guidelines are 20 years out of date and more importantly can adversely impact on the health of patients (eg graded exercise therapy) As you know our NCNED researchers are leading the way in the establishment of the Clinical Guidelines and the UK and USA(see description of activities below) but there is no activity on Australian guidelines. We understand the framework for successful

implementation, we have the expertise to achieve these guidelines but to be successful the Government needs to support this work.

With reference to your previous email, the first clinical guidelines document underway is implemented through the British Medical Journal as the UK guidelines for ME/CFS mirroring recent adaptation of the ME/CFS National Institute for Health and Care Excellence (NICE) guidelines undertaken according to "[Developing NICE guidelines: the manual](#)". The development of these guidelines has so far been achieved through a consultation process with medical professionals, including psychiatrists given ME/CFS was originally labelled as a psychiatric illness before now being characterised as a neurological disease under the International Classification of Diseases version 11. I assisted with facilitating this re-classification through my position as the only Australian on the Board of Directors of the International Association for ME/CFS.

Furthermore, the consultation process has been with medical professionals (via BMJ), Professor Baraniuk and Professor Don Staines. This has ensured the potential challenges that have been evident with previous iterations over the years were mitigated. For example, the removal of detrimental treatment recommendations such as Graded Exercise Therapy and Cognitive Behavioural Therapy (GET/CBT), which were raised on Tuesday. Under these new BMJ guidelines being constructed by myself, Dr Natalie Eaton-Fitch and Dr James Baraniuk, GET/CBT has been removed from the treatment algorithm and instead labelled as treatment of uncertain efficacy lacking evidence of benefit. In addition, further mitigation has also entailed peer-reviewed clinical and research evidence obtained internationally and collated through a series of systemic reviews undertaken. The BMJ follows internationally consistent guideline development protocols whereby guidelines are developed by unbiased experts with consultation of expert multidisciplinary organisations (organised through BMJ) before publication and subsequently undergoes annual and bi-annual review. Additionally, these guidelines implemented through BMJ had limited consumer stakeholders. Importantly, stakeholder and end-user engagement is undertaken using a series of overlapping protocols internationally (as published by the NHMRC, NICE, and NIH etc). In recent years, the NHMRC has advocated for stakeholder engagement and consumer consultation when developing guidelines given only 14% of guidelines published between 2005-2013 reported consumer involvement.

Our second document being constructed with the National Academies in the US has addressed the stakeholder involvement through the establishment of a committee comprising of national patient advocacy groups, clinicians, and specialist ME/CFS clinicians, as well as biomedical researchers. This approach is outlined by the Institute of Medicine (IOM) "[Clinical Practice Guidelines We Can Trust](#)". The initiation of their process began with consultation with focus groups to identify gaps in diagnosis, treatment and care to organise the collation of evidence to support the development of these new ME/CFS clinical guidelines. NCNED is now writing and to be delivered at the latter part of 2023 for the committee to endorse, followed by implementation through these networks and agencies. Thus, all stakeholders are fully engaged and endorse the adaptation of these new guidelines for implementation through US health services and agencies, such as the CDC and NIH for timely action to benefit health consumers.

Hence, the two guidelines we are constructing provides for international standardisation and uniformity, for example the classification of GET/CBT as treatments with uncertain efficacy and lacking evidence of benefit. While we refer to the abovementioned independent processes, the challenges identified during the BMJ Guideline development have been addressed in the National Academies Guidelines, ensuring successful uptake and implementation. Moreover, the approach we have taken with the National Academies enables the “least path of resistance” that we could adopt her in Australia. The proposed new Clinical Guidelines for Australia would also provide for additional up-take through the ME/CFS Primary Health Network Model that is currently underway in QLD, however this could be implemented in other states and territories of Australia.

We believe it is pertinent to highlight that there has been no substantial funding provided to undertake these guidelines and there is no potential for these international agencies to support the Australian guidelines. Our expertise and the protocols identified through undertaking these international guidelines provide the ability for us to refine and implement a seamless process from design, development and implementation in Australia.

Given our international expertise and given the clinical guidelines models we have been requested to deliver, and knowing the landscape of the Australian ME/CFS environment (both patient and clinical) we have the capability to deliver a new ME/CFS Clinical Guidelines ensuring a successful outcome to the Australian Federal Government that promotes international uniformity and standardisation.

NCNED seeks direction to submit a proposal to deliver these new and timely ME/CFS Guidelines to improve the lives of 250,000 Australians (plus emerging cases).

All our very best.

Sonya

From: CARLILE, Chris <s22 [REDACTED]@health.gov.au>

Sent: Friday, 16 June 2023 8:07 AM

To: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>

Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>

Subject: RE: NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile [SEC=OFFICIAL]

Sonya

Many thanks for the email and the attached documentation.

It was a pleasure to be able to attend a very informative launch of the Parliamentary friends of ME/CFS. I want to acknowledge the work that you are doing towards developing ME/CFS guidelines.

Thank you for the information you have provided both in hard copy and electronically.

I would also be interested to learn of the final outcomes of your work.

Kind regards

chris

From: Sonya Marshall-Gradisnik <s.marshall-gradisnik@griffith.edu.au>
Sent: Thursday, 15 June 2023 2:45 PM
To: CARLILE, Chris <[s22\[REDACTED\]@health.gov.au](mailto:s22[REDACTED]@health.gov.au)>
Cc: Natalie Eaton-Fitch <n.eaton-fitch@griffith.edu.au>
Subject: NCNED ME/CFS Friends of Parliament: Attention Mr Chris Carlile

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.

Dear Chris,

Thank you for taking the time to attend the Friends of Parliament for ME/CFS, June 13,2023.

I, along with Professor Staines and S47F were very thankful you were so generous with your time and spoke with us in detail regarding our biomedical, clinical and economic work in the field of ME/CFS.

The National Centre for Neuroimmunology and Emerging Diseases (NCNED) employs a ME/CFS patient- researcher- clinician model, a unique model that has positioned us as the world leader in the field of ME/CFS and more recently Long COVID.

The NCNED brief that is attached to this email (also provided to you in hardcopy at the Friends of Parliament for ME/CFS meeting) details key achievements and our world leading standing/recognition. As indicated to you, Dr Eaton-Fitch and I, along with our collaborator Dr James Baraniuk, Georgetown University (USA), were invited to write the New ME/CFS Clinical Guidelines for the British Medical Journal (UK). Moreover, my expertise, Dr Eaton-Fitch and Professor Staines' expertise in this field has been recognised by the US Health Services through the National Academy of Medicine and Science to write the report for the clinical guidelines and research direction for ME/CFS, FM and Long COVID. Our expertise, in conjunction with our strong collaborative relationship with ME/CFS stakeholders nationally and internationally has enabled us to identify and mitigate potential challenges to ensure successful delivery of these guidelines to benefit ME/CFS patients and medical professionals with the aim to reduce the cost to the Health Care System. Presently in Australia the annual health care costs are \$14.1 billion (NCNED research that was quoted by the second speaker at this event on Tuesday). New ME/CFS Australian Guidelines would provide for global standardisation and unification, a first for this disease.

I, along with Professor Staines, are co-authors of the International Case Definition for ME/CFS, hence, we are well position for additional alignment in the international context.

The impact of our research and clinical findings have underpinned the successful QLD Health Pathway for ME/CFS program piloted in the West Moreton District (QLD). This has now gone "live" for QLD and is implement through the Primary Health Network (ME/CFS- PHN).

Our QLD ME/CFS-PHN model is an exemplar to deliver a national health service for ME/CFS.

We would be delighted to continue our discussions with you and your staff.

Thank you for taking the time to read this email.

Best wishes

Sonya

Dr Sonya Marshall-Gradisnik

Inaugural Stafford Fox Medical Research Foundation ME/CFS

Professorial Research Fellowship

Professor Immunology

Director: National Centre for Neuroimmunology and Emerging Diseases

Program Director: Disability and Rehabilitation

Menzies Health Institute Queensland

Griffith University | Gold Coast Campus | QLD 4111 | s47F

T +61 7 5678 0725

M s47F

E s.marshall-gradisnik@griffith.edu.au

This document has been released under
the Freedom of Information Act 1982
by the Department of Health and Aged Care



"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 and Aged Care

s22

s22

From: s22 s22 s22
Sent: Saturday, July 20, 2024 5:43 PM
To: Butler, Mark (MP) <Mark.Butler.MP@aph.gov.au>
Subject: Form Submission - Contact Form - Health

s22

Sent via form submission from [Mark Butler MP](#)

Name: s47F

Email: s47F @outlook.com

Phone: s47F

State/Territory: s47F

Suburb: s47F

Postcode: s47F

Message: Dear Minister Butler,
Thanks for your great work.

I sit as s47F on a not-for-profit Foundation registered with the ACNC, with DGR status granted by the ATO.

The Foundation is a Sponsor in the only TGA approved Clinical trial in Australia, headed by Dr Andrew Lucas, to determine if EBOO ozone can treat ME/CFS .

I also note that you are in the process of revamping the clinical guidelines that are over 20 years old at the moment. It's great news that these outdated clinical guidelines are being looked at.

I am concerned that more than 250,000 Australians are affected by this condition, yet we cannot obtain funds to start this critical clinical trial.

I was hoping your department may assist us.

I can provide further details if necessary.

I look forward to hearing from you shortly,

s47F

This document has been released under the Freedom of Information Act 1982 by the Department of Health and Aged Care

[Manage Submissions](#)

Does this submission look like spam? [Report it here.](#)

This document has been released under
the Freedom of Information Act 1982
by the Department of Health and Aged Care

Ref No: MC24-011562

s47F
s47F @outlook.com

Dear s47F

Thank you for your correspondence of 20 July 2024 to the Minister for Health and Aged Care, the Hon Mark Butler MP, regarding funding for a clinical trial to explore the potential of EBOO ozone as a treatment for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). The Minister has asked me to reply.

As you referenced, the Government is responding to the need for better support for people with ME/CFS, Long COVID, and related conditions by allocating \$1.1 million to the National Health and Medical Research Council (NHMRC) to develop new Australian clinical guidelines. These guidelines will be developed in collaboration with patient groups, health professionals, and medical scientists.

Regarding your question about clinical trials, the Government directly supports health and medical research through the complementary Medical Research Future Fund (MRFF) and the NHMRC. The NHMRC is the Australian Government's primary funding body for health and medical research.

It's important to note that the majority of NHMRC funding is not allocated to any specific disease, discipline, or health issue. The subject matter of each investigator-initiated application is determined by the applicants based on the expertise and research interests of those applying for funding. Research teams decide their research area and strategy prior to submitting an application to receive NHMRC funding. The NHMRC welcomes all grant applications relevant to human health through our established research-funding mechanisms. More information is available through the NHMRC website at: www.nhmrc.gov.au/.

Additionally, the MRFF's Preventive and Public Health Research initiative offers funding for research that tests innovative approaches to preventive and public health issues in Australia. It will provide \$596.5 million over 10 years from 2022-23 for research projects that address risk factors that contribute to chronic and complex diseases in Australia.

Through the MRFF's Clinical Trials Activity Initiative and Emerging Priorities and Consumer Driven Research Initiative, up to \$18 million in funding was available for the 2022 Multiple Sclerosis Research grant opportunity. Applications for ME/CFS grants were able to be made under Stream 3 and 4 of this Grant Opportunity. More information on funding opportunities can be found through the Department of Health and Aged Care website, at www.health.gov.au/our-work/mrff.

Thank you for writing on this matter. I wish you the very best of success with your research funding applications.

Yours sincerely,

s47F

s22

Director - Chronic Conditions Projects
Hearing Services and Chronic Conditions Branch
Cancer, Hearing and Chronic Conditions Division
20 August 2024

This document has been released under
the Freedom of Information Act 1982
by the Department of Health and Aged Care