



November 3, 2020

Walter J. Koroshetz, M.D.  
Director, National Institute of Neurological Disorders and Stroke  
National Institutes of Health

Dear Dr. Koroshetz,

#MEAction looks forward to receiving ME/CFS program updates and asking questions at the National Institutes of Health (NIH)'s upcoming telebriefing on Thursday, November 5, 2020.

Stakeholder engagement is essential because what is at stake for us in the ME/CFS crisis is nothing less than our lives. Given the likelihood that many new people will develop ME/CFS after COVID-19, now is the time for robust stakeholder engagement. Our community brings decades of expertise and lived experience with this disease. We remain eager to collaborate with the NIH, as equal partners, in ensuring the delivery of scientific research, medical education, and compassionate clinical care for people with ME.

We submit these comments and questions in advance of the telebriefing in order to assist the trans-NIH team in preparing relevant updates for the community. While we expect sufficient time to be allocated to progress updates and community questions, we understand that you may not be able to address every question during this call. We welcome timely responses by email or an alternative venue for discussion where our questions may be addressed in more detail.

The NIH has a crucial role in addressing the complex scientific research challenges that confront ME/CFS. Decades of stigma, misinformation and neglect continue to harm people with ME. We need a NIH response that is urgent, comprehensive and proactive. It must address critical issues and dedicate the necessary resources. People with ME deserve nothing less.

Sincerely,

Ben HsuBorger  
Campaigns Director  
#MEAction

## Incorporating ME/CFS Knowledge in Upcoming NIH Workshop

We understand from Dr. Fauci that the [Workshop on Post-Acute Sequelae of COVID-19](#), taking place December 3 and 4, will be an important part of the NIH Leadership Forum's work moving forward. Given the import of this event, we have several questions:

### **Questions:**

1. Can you tell us the concrete products you see arising from this workshop? Insofar as the workshop will inform a Long COVID research agenda, what is being done to ensure that knowledge about post-viral, multi-system illnesses, available through ME/CFS research to date, is fully utilized to inform future research plans?
2. One of the stated goals of this workshop is to "identify key knowledge gaps that are necessary to address." A number of long-haulers are reporting experiences of post exertional malaise, and yet understanding of this debilitating symptom is sparse among researchers and clinicians. Thank you so much for the recent research article on this topic [published in "Frontiers of Neurology."](#) How do you plan to introduce post exertional malaise as a key knowledge gap within the context of this workshop?
3. Will there be ME/CFS experts presenting at the workshop? What are you doing to ensure these experts are invited and encouraged to attend this workshop? As their representation is central to this forum, can you commit to proactively reaching out to them with invitations?
4. Given how little is known about COVID-19 sequelae, it is extremely important that the NIH design research that integrates reported lived experience needs. How will the workshop address the role of patient input in the characterization of post-acute sequelae of COVID-19?

## Advancing Progress at Collaborative Research Centers

Advance research at the CRCs: The three existing CRCs have begun contributing invaluable research on ME/CFS, but they are nearing the end of their grant period, and the pandemic has greatly disrupted their research plans in 2020. It is critical that the NIH not only ensures the continuation of their work past 2021, but expands it as well.

Grow the CRC Network through RFAs: There was demand for additional CRCs even prior to COVID (only 3 of 10 CRC proposals were accepted); this demand is even greater now. RFAs would swiftly and effectively address the current research shortage, and expand ME/CFS research efforts in a demonstrable manner.

### **Questions:**

5. Does NIH have plans to continue funding the three current CRCs beyond 2021?

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6. Will you commit to releasing an RFA to fund additional CRCs required to meet ME/CFS research needs in this time period?
7. It has now been almost three years since the CRCs started, with research well underway, but the Community Advisory Committee (CAC) is only now launching. Given this limitation, what impact do you expect the CAC to have, and how will this be achieved?

### Clarifying Intramural ME/CFS Patient Recruitment Plans

We are glad to hear that a NIH intramural research study into post COVID-19 is now recruiting new patients, and that it will eventually coincide with the intramural ME/CFS study. But given that NIH has said they were [struggling to recruit enough patients to participate in the ME/CFS study](#), we are concerned to hear reports that the study may no longer be planning on recruiting and bringing in new patients.

#### **Questions:**

8. How many ME/CFS patients and controls have been seen thus far in the study and when are you expecting to start bringing patients into the Clinical Center again?
9. If the recruitment goals for the ME/CFS study are being changed, how is that expected to impact the statistical power of study findings, and what plans are being made to ensure that study findings will be robust enough to publish?
10. When do you expect to publish findings from the ME/CFS study?

### Identifying ME/CFS Inter-agency Working Group Stakeholder Engagement Opportunities

The Interagency ME/CFS Working Group (IAWG) was a recommended strategy of the [Report on the NANS Working Group for ME/CFS Research](#). Its stated purpose is to identify ME/CFS-related questions and issues and work together on solutions. We are encouraged that this working group includes not only NIH and Centers for Disease Control and Prevention (CDC), but several other federal agencies as well<sup>1</sup>, and we commend you for ensuring robust inter-agency participation.

Nevertheless, we are concerned about this working group's inadequate stakeholder engagement to date. Advocacy non-profit organizations have been told they will have no set membership in this working group and will only be invited to specific meetings when NIH decides they should be allowed to participate. There has been only a single 2-hour public meeting on August 11 and since then no further information has been provided about the next steps for this working group.

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<sup>1</sup> These include: Congressionally Directed Medical Research Programs (CDMRP) at the Department of Defense (DoD), Veterans Affairs (VA), Department of Education (DoE), and the Social Security Administration (SSA).

## #MEAction comments & questions for the Nov. 5, 2020 trans-NIH ME/CFS telebriefing

#MEAction wants to engage collaboratively and constructively with NIH and the other federal agencies in tackling the complex challenges ME/CFS faces, but to do so we need more than superficial engagement.

### Questions:

11. #MEAction has heard nothing about the IAWG since the launch meeting on August 11, 2020. Has the IAWG met privately since then? Have they started to work together further and if so, what have they accomplished?
12. What IAWG subcommittees will be formed? What issues are being prioritized? What central goals do subcommittees aim to achieve?
13. Will #MEAction, and other community stakeholders, be given any opportunity to give input into the development of working group plans?
14. When is the next IAWG public meeting?
15. When, how, and how often will organizations like #MEAction be notified with updates and invitations to participate in future IAWG projects?

## Accelerating ME/CFS Research in the era of Long COVID<sup>2</sup>

Address stagnant NIH funding: ME/CFS research funding for 2019 was only \$13.1M.<sup>3</sup> We are concerned about the stagnant ME/CFS funding levels at NIH, particularly in the wake of the long COVID crisis. ME/CFS research may hold keys to understanding some of the long-term health consequences of COVID-19<sup>4</sup>, like no other area of research can. It is therefore time to break the decades-long pattern of underfunding ME/CFS research.

Stimulate extramural research: In 2020, the NIH issued only two new extramural ME/CFS grants. Clearly, the NIH needs high-level strategy and large-scale resource infusion to stimulate ME/CFS research activity. RFAs provide the necessary encouragement to eligible researchers

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<sup>2</sup> ME/CFS research remains significantly underfunded and must be raised at least 15-fold - to over \$200M per year - to be commensurate with the burden of the disease. Funding for ME/CFS has actually declined slightly since the CRCs were formed 3 years ago, and there are no planned increases in sight. This represents a health equity issue that must be addressed now, and it can best be addressed by setting aside research funding dedicated to ME/CFS.

<sup>3</sup> ME advocate Jennie Spotila analyzed NIH ME/CFS research funding for 2019 and found that while the NIH reported \$15.2M in spending, actual spending was only \$13.1M, 14% less; the NIH program staff have confirmed this fact-checking. We understand that you are working to improve the accuracy of reported ME/CFS spending figures within the limitations of NIH's budget categorization process.

<sup>4</sup> [Experts have discussed](#) how ME/CFS research has produced the most advanced knowledge on multi-system post-viral illness to date, and it therefore could hold the keys to understanding the long-term health consequences of COVID-19.

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and help correct for the decades of stigma and underfunding in the field of ME/CFS. Particularly in the era of long COVID, stimulating ME/CFS research is essential.

### **Questions:**

16. Given the centrality of ME/CFS research in the era of Long COVID, what is NIH doing to reverse this continuing trend of stagnant ME/CFS funding?
17. Will NIH rapidly accelerate ME/CFS research by utilizing the various grant mechanisms at their disposal, such as issuing new RFAs, PARs, NOSIs, and expedited grant review?
18. Will NIH focus a selection of these mechanisms to address the intersection of ME/CFS and Long COVID, about which top experts including Dr. Fauci have identified as in need of further study?

## Catalyzing Necessary Clinical Treatment Trials

In Dr. Koroshetz's October interview with [MedPage Today](#), he said the urgent needs of hundreds of thousands of COVID-19 survivors calls for some trials of available recovery and rehabilitation treatments to start now to inform their medical care, and that time is of the essence in this pursuit. ME/CFS researchers and clinicians have long identified potential effective treatments for ME/CFS, many of which are already FDA-approved.<sup>5</sup> These may help prevent chronicity in a subset of long-haulers, but additional testing is needed.

[ME/CFS expert clinicians](#) have also increased the quality of life for many people with ME/CFS through dozens of symptom-reducing treatments that have still not been evaluated for safety, efficacy, and subgroup relevance in clinical trials because of chronic lack of funding and NIH support. We urge NIH to use the ME/CFS research and clinician expert knowledge base to rapidly execute clinical trials of these and other drugs to help long-haulers and people with ME/CFS.<sup>6</sup>

### **Questions:**

19. Will you consider rapidly executing clinical trials of treatments, identified by ME/CFS researchers and expert clinicians as priorities for study? These may also help a subset of COVID-19 long-haulers, particularly at the beginning of their illness.

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<sup>5</sup> Some of the FDA-approved treatments include antivirals, anti-inflammatories, plasmapheresis and IVIG. Drugs that have worked in the nanoneedle, such as SS31, copaxone, and suramin have not been used clinically but could also be effective. All require additional testing.

<sup>6</sup> While we may not understand the biological mechanisms well enough to pursue "rational drug design" of treatments against defined targets (where you have the target already identified and you design a drug to interact with that target), ME/CFS clinicians have substantial experience with repurposing approved drugs to treat symptoms and improve patients' quality-of-life. Well-designed clinical trials of these therapies can help refine outcome measures and study design approaches, and clarify key disease subsets. Such studies could also reveal the underlying mechanisms of the disease.

## #MEAAction comments & questions for the Nov. 5, 2020 trans-NIH ME/CFS telebriefing

20. Will you commit to including ME/CFS comparison groups in your long COVID clinical trials?
21. How do you plan to leverage the existing [COVID-19 prevention trials network](#) to execute this critical work?

### Understanding Data Management Coordinating Center Goals

One of the main goals of the ME/CFS Data Management Coordinating Center is to integrate diverse data sets from the CRCs to gain insights into patient care.

#### Questions:

22. What specific goals do you see the DMCC platform achieving to advance ME/CFS clinical care in the next 2 years?
23. How have these goals shifted or changed since the emergence of Long COVID? Given the potential applicability of these datasets to some Long COVID researchers, are there plans for proactive outreach to the wider research community regarding this network?
24. Given that this initiative will launch a public website to more efficiently advance knowledge in the ME/CFS field, it will be important to gather patient and stakeholder input to inform design and outcome goals. What plans does the DMCC have for enlisting patient partners to inform their work?