DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

August 30, 2013

Dear Ms. Pearson,

Thank you for forwarding the letter on behalf of the numerous patient organizations and individual patient advocates who were signatories. I have also received many individual emails expressing the heartfelt concern of the CFS community about the CDC multi-site clinical study. CDC initiated the multi-site study specifically because of the needs cited in your letter and similar feedback we have received from patients and clinicians over the years.

We agree that biologic measures are crucial to further characterize and sub-group patients. To assure the quality of sample collection and measures we first needed to establish the effectiveness of a multi-site working group. We did this and more in our first stage of the study that successfully enrolled and collected self-reported measures on over 450 CFS patients. Our plans for the next stages of the study are briefly outlined in a separate page (attached).

To address concerns regarding the cardio-pulmonary exercise testing (CPET) in the second stage of the study, I would like to share additional details, and the rationale that we used to select the one-day maximal exercise test. Our primary objective is to measure the exercise capacity in as many of the enrolled patients as possible using a standardized protocol, and to monitor the post-exertional response for 48 hours with online cognitive testing and visual analogue scales of fatigue, pain, and symptoms. Maximal CPET with one day of testing and 48-hour follow-up of cognition was developed in consultation with Dr. Gudrun Lang (cognition) and Dr. Dane Cook and Connie Sol (exercise). The exercise protocol was discussed also with Dr. Chris Snell. Dr. Snell favors the two-day test because it gives more information, however he believes the one-day maximal CPET will provide useful information. We chose the one-day test so that more patients could be tested. The two-day test would require an additional overnight stay for those patients who travel long distances to attend clinic and excludes those who are most severely affected because of the heavy physical toll. In developing the protocol, we strived to find a balance between testing that would yield meaningful data in the broadest representation without placing an unnecessary burden on the patients.

We appreciate the commitment and hard work of our clinician experts, as well as the generous and selfless participation of the patients who are essential to the success of this project. This is a long overdue partnership, and we hope that the data and samples collected will advance additional clinical and scientific studies identifying biologically-based subgroups and therapeutic targets.

Sincerely,

Elizabeth R. Unger

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