# Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM)

Request for OMB approval of an Existing Collection in Use without an OMB Control Number

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**Supporting Statement B**

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# Table of Contents

1. Respondent Universe and Sampling Methods.....2
2. Procedures for the Collection of Information.....2
3. Methods to maximize Response Rates and Deal with No Response.....3
4. Tests of Procedures or Methods to be Undertaken.....3
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....3

This collection of information involves statistical methods including descriptive statistics, and general or generalized linear models. The purpose of the collection is to describe the illness heterogeneity of patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and identify patient subgroups based on their common characteristics using a multi-site study sample recruited from ME/CFS specialty clinics in the United States. Statistical generalizations will not be made beyond the patient population in the tertiary setting (ME/CFS specialty clinics).

## 1. Respondent Universe and Sampling Methods

The respondent universe consists of patients from ME/CFS specialty clinics and their physician networks in the United States [Open Medicine Institute Consortium, CA; Mount Sinai Beth Israel, NY; Institute for Neuro-Immune Medicine, FL]. These specific clinics were chosen because they are well-known with physicians experienced in caring for patients with ME/CFS.

The MCAM study has been conducted in multiple stages. At Stage 1, we aimed to enroll 450 ME/CFS patients in a 1-year timeframe using a standardized approach. Sample size was primarily constrained by budget and feasibility of the study management at each clinical site. On the basis of previous ME/CFS clinical studies, we anticipated a follow-up rate of 75%, resulting in a total of 338 patients for whom we would collect complete data (≥80% of valid data via instruments/forms) and who would be eligible for the follow-up of ME/CFS subjects at stage 2. Based on an effect size of 0.4, a minimum of 130 subjects were needed in the ill comparison group to achieve 90% power to detect a 2-point difference in mean Multidimensional Fatigue Inventory subscale scores and a 12-point difference in the mean 36-Item Short Form Survey subscale scores between the ME/CFS and other illnesses (or ill comparison) groups. A healthy control group of equal size was recruited for group comparisons of ME/CFS illness domain measures.

## 2. Procedures for the Collection of Information

This collection of information does not involve stratification and sample selection. Respondents are patients seen at the selected clinics. Authorized and trained study personnel review participant medical records to abstract information on medical/family history, infection and immunization history, medications, laboratory and test results at the first and most recent visits to the clinic. For self-administered questionnaires/instruments, participants respond to the questions via a web-based system (OpenMedNet, Open Medicine Institute) or a paper form before or at the next clinic visit.

### 3. Methods to maximize Response Rates and Deal with No Response

Standardized instruments and tests are administered through several modes (paper form or web-based form on mobile, tablet, or PC devices) to reduce non-responses due to technology. Monitoring response rates of this information collection is done through conference calls on a regular basis with the coordinating center, Open Medicine Institute Consortium and each clinical site, offering the opportunity to share strategies for improving response rates. CDC's Epidemiology Data Management, and Analysis (EDMA) team conducts weekly checks on data collection via web-based system and paper copies throughout the collection period. Annual site visits to the clinics and reversed site visits to CDC from the clinics increases and maintains site involvement. Additionally, the study sites send out study newsletters every other year to assist in retention of data collection at follow-up visits and promote future data collection follow-up visits.

### 4. Tests of Procedures or Methods to be undertaken

The data/information collection forms and procedures have been used in ME/CFS studies or studies in other illnesses. Therefore, we did not conduct pilot testing for this data collection. However, we conducted a practice session with about 8 staff members and refined standard operation procedures for administering standardized instruments and tests used in this information collection.

### 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

We have consulted with the following individuals on statistical aspects of the design and instrument measures.

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The following staff at American Istitute for Research (AIR) provided consultation and analysis for the data on measures from Patient-Reported Outcomes Measurement Information System (PROMIS) and can be reached at the following address and phone number:

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