



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-20QS]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Proposed Data Collection Multi-Site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a 60-day notice titled "Proposed Data Collection Submitted for Public Comment and Recommendations" on August 3, 2020 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Multi-Site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM) - Existing collection in use without an OMB Control Number - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM) study uses a standardized approach for data collection to examine the heterogeneity of patients with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) using a clinical epidemiologic longitudinal study with a retrospective and prospective rolling cohort design. The study also aims to address the issue of ME/CFS case definition and improve measures of illness domains by using evidence-based data from multiple clinical practices in the United States. Healthy adults and those with illnesses that share some features with ME/CFS were enrolled in comparison groups. Children and adolescents with ME/CFS and healthy participants were also enrolled.

The MCAM study has been conducted in multiple stages following multiple study protocols. The time burden estimates are based on the 2012-2019 data collection, which is the most recent stage of data collection completed.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Participants	No. of Responses per Participant	Average Burden per Response (in hrs.)
Adult	CDC Symptom Inventory (CDC-SI)/Form A	45	1	12/60
Adult	CDC Symptom Inventory (CDC-SI)/Form B	20	1	10/60
Adult	CDC Symptom Inventory (CDC-SI)	20	1	8/60
Adult	Short Form CDC-SI/Checklist	85	1	10/60
Adult	Medical Outcomes Study Short Form 36	85	1	7/60
Adult	Multidimensional Fatigue Inventory (MFI-20)	85	1	5/60
Adult	DePaul Symptom Questionnaire (DSQ)	45	1	24/60
Adult	DSQ, 26 selected questions	65	1	12/60
Adult	DSQ, 18 selected questions	85	1	6/60
Adult	PROMIS Short Form (PROMIS SF - Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form	85	1	5/60
Adult	PROMIS SF - Fatigue, SD, SRI, PB, PI	85	1	4/60
Adult	Brief Pain Inventory (BPI)	85	1	13/60
Adult	Patient Health Questionnaire (PHQ-8), Generalized Anxiety Disorder (GAD-7), CDC Health-Related Quality of Life (HRQoL-4)	85	1	10/60
Adult	CDC HRQoL-4	85	1	3/60
Adult	CDC HRQoL-4 with activity limitation questions	85	1	4/60
Adult	Self-Rating Depression Scale (SDS)	45	1	7/60
Adult	Illness Impact Questionnaire	85	1	3/60
Adult	Saliva Data Collection Sheet	85	1	5/60
Adult	Orthostatic Grading Scale (OGS)	85	1	3/60
Adult	COMPOSITE Autonomic Symptom Score 31 (COMPASS-31)	85	1	5/60
Adult	CDC Symptom Inventory (CDC-SI)/Form A	24	1	42/60
Adult	CDC Symptom Inventory (CDC-SI)/Form B	30	1	20/60
Adult	CDC Symptom Inventory (CDC-SI)	15	1	10/60
Adult	Short Form CDC-SI/Checklist	69	1	20/60

Adult	Medical Outcomes Study Short Form 36	69	1	17/60
Adult	Multidimensional Fatigue Inventory (MFI-20)	69	1	10/60
Adult	DePaul Symptom Questionnaire (DSQ)	24	1	36/60
Adult	DSQ, 26 selected questions	45	1	18/60
Adult	DSQ, 18 selected questions	69	1	20/60
Adult	PROMIS Short Form (PROMIS SF - Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form	24	1	6/60
Adult	PROMIS SF - Fatigue, SD, SRI, PB, PI	69	1	5/60
Adult	Brief Pain Inventory (BPI)	24	1	13/60
Adult	Patient Health Questionnaire (PHQ-8), Generalized Anxiety Disorder (GAD-7), CDC Health-Related Quality of Life (HRQoL-4)	24	1	10/60
Adult	CDC HRQoL-4	69	1	4/60
Adult	CDC HRQoL-4 with activity limitation questions	69	1	7/60
Adult	Self-Rating Depression Scale (SDS)	24	1	7/60
Adult	Illness Impact Questionnaire	69	1	3/60
Adult	Saliva Data Collection Sheet	69	1	5/60
Adult	Orthostatic Grading Scale (OGS)	69	1	5/60
Adult	COMPOSITE Autonomic Symptom Score 31 (COMPASS-31)	69	1	7/60
Pediatric	CDC Symptom Inventory: For Baseline Subjects Pediatrics	36	1	8/60
Pediatric	CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics	29	1	6/60
Pediatric	SF-36 Health Survey	64	1	5/60
Pediatric	Multidimensional Fatigue Inventory (MFI-20)	64	1	2/60
Pediatric	Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions	64	1	5/60
Pediatric	PROMIS Pediatric Instruments (Fatigue & Pain)	64	1	2/60
Pediatric	Pediatric Pain Questionnaire (PPQ)	64	1	7/60
Pediatric	Visual Analogue Scale	64	1	6/60
Pediatric	Hospital Anxiety and Depression Scale	64	1	5/60
Pediatric	Pediatric Daytime Sleepiness Scale	64	1	2/60

Pediatric	Social Participation Form Pediatric	64	1	7/60
Pediatric	Sociability Form	64	1	3/60
Pediatric	Saliva Collection Form	64	1	5/60
Pediatric	CDC Symptom Inventory: For Baseline Subjects Pediatrics	3	1	20/60
Pediatric	CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics	3	1	9/60
Pediatric	SF-36 Health Survey	3	1	9/60
Pediatric	Multidimensional Fatigue Inventory (MFI-20)	3	1	7/60
Pediatric	Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions	3	1	10/60
Pediatric	PROMIS Pediatric Instruments (Fatigue & Pain)	3	1	3/60
Pediatric	Pediatric Pain Questionnaire (PPQ)	3	1	15/60
Pediatric	Visual Analogue Scale	3	1	8/60
Pediatric	Hospital Anxiety and Depression Scale	3	1	7/60
Pediatric	Pediatric Daytime Sleepiness Scale	3	1	3/60
Pediatric	Social Participation Form Pediatric	3	1	10/60
Pediatric	Sociability Form	3	1	5/60
Pediatric	Saliva Collection Form	3	1	5/60
Adult	CogState Practice Section	109	1	17/60
Adult	CogState Baseline Section	109	1	27/60
Adult	WAIS IV DS F+B, TOPF	109	1	10/60
Adult	Exercise (Bike) Testing	64	1	30/60
Adult	CogState Time 1 Section	109	1	22/60
Adult	CogState Time 2 Section	109	1	12/60
Adult	CogState Time 3 Section	109	1	12/60
Adult	CogState Time 4 Section	109	1	12/60
Adult	Visual Analogue Scale for CFS Symptoms	60	1	8/60
Adult	EQ-5D-Y Health Questionnaire	60	1	6/60
Adult	PROMIS SF v1 - Physical Function	60	1	5/60
Adult	Physical Fitness and Exercise Activity Levels of Scale	60	1	2/60
Adult	International Physical Activity Questionnaire (Self- Administered Long Form)	60	1	5/60
Adult	Physical Activity Readiness Questionnaire	60	1	5/60
Adult	Visual Analogue Scale for CFS Symptoms	49	1	8/60

Adult	EQ-5D-Y Health Questionnaire	49	1	6/60
Adult	PROMIS SF v1 - Physical Function	49	1	5/60
Adult	Physical Fitness and Exercise Activity Levels of Scale	49	1	2/60
Adult	International Physical Activity Questionnaire (Self-Administered Long Form)	49	1	5/60
Adult	Physical Activity Readiness Questionnaire	49	1	5/60

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