



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20QS; Docket No. CDC-2020-0086]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM). This collection is designed to assess and characterize illness heterogeneity of Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome (ME/CFS), and uses a standardized approach including standardized protocols with standardized tests and instruments to collect data on patients from multiple clinical practices.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0086 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

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 | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---------------------|---|-----------------------|------------------------------------|--|-------------------------|
| Adult | CDC Symptom Inventory (CDC-SI)/Form A | 45 | 1 | 12/60 | 9 |
| Adult | CDC Symptom Inventory (CDC-SI)/Form B | 20 | 1 | 10/60 | 3 |
| Adult | CDC Symptom Inventory (CDC-SI) | 20 | 1 | 8/60 | 3 |
| Adult | Short Form CDC-SI/Checklist | 85 | 1 | 10/60 | 14 |
| Adult | Medical Outcomes Study Short Form 36 | 85 | 1 | 7/60 | 10 |
| Adult | Multidimensional Fatigue Inventory (MFI-20) | 85 | 1 | 5/60 | 7 |
| Adult | DePaul Symptom Questionnaire (DSQ) | 45 | 1 | 24/60 | 18 |
| Adult | DSQ, 26 selected questions | 65 | 1 | 12/60 | 13 |
| Adult | DSQ, 18 selected | 85 | 1 | 6/60 | 9 |

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|-------|--|----|---|-------|----|
| | questions | | | | |
| Adult | PROMIS Short Form (PROMIS SF - Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form | 85 | 1 | 5/60 | 7 |
| Adult | PROMIS SF - Fatigue, SD, SRI, PB, PI | 85 | 1 | 4/60 | 6 |
| Adult | Brief Pain Inventory (BPI) | 85 | 1 | 13/60 | 18 |
| Adult | Patient Health Questionnaire (PHQ-8), Generalized Anxiety Disorder (GAD-7), CDC Health-Related Quality of Life (HRQoL-4) | 85 | 1 | 10/60 | 14 |
| Adult | CDC HRQoL-4 | 85 | 1 | 3/60 | 4 |
| Adult | CDC HRQoL-4 with activity limitation questions | 85 | 1 | 4/60 | 6 |
| Adult | Self-Rating Depression Scale (SDS) | 45 | 1 | 7/60 | 5 |
| Adult | Illness Impact Questionnaire | 85 | 1 | 3/60 | 4 |
| Adult | Saliva Data Collection Sheet | 85 | 1 | 5/60 | 7 |
| Adult | Orthostatic Grading Scale (OGS) | 85 | 1 | 3/60 | 4 |
| Adult | COMPOSITE Autonomic Symptom Score 31 (COMPASS-31) | 85 | 1 | 5/60 | 7 |
| Adult | CDC Symptom Inventory (CDC-SI)/Form A | 24 | 1 | 42/60 | 17 |
| Adult | CDC Symptom Inventory (CDC-SI)/Form B | 30 | 1 | 20/60 | 10 |
| Adult | CDC Symptom | 15 | 1 | 10/60 | 3 |

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|-------|--|----|---|-------|----|
| | Inventory (CDC-SI) | | | | |
| Adult | Short Form CDC-SI/Checklist | 69 | 1 | 20/60 | 23 |
| Adult | Medical Outcomes Study Short Form 36 | 69 | 1 | 17/60 | 20 |
| Adult | Multidimensional Fatigue Inventory (MFI-20) | 69 | 1 | 10/60 | 12 |
| Adult | DePaul Symptom Questionnaire (DSQ) | 24 | 1 | 36/60 | 14 |
| Adult | DSQ, 26 selected questions | 45 | 1 | 18/60 | 14 |
| Adult | DSQ, 18 selected questions | 69 | 1 | 20/60 | 23 |
| Adult | PROMIS Short Form (PROMIS SF - Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form | 24 | 1 | 6/60 | 2 |
| Adult | PROMIS SF - Fatigue, SD, SRI, PB, PI | 69 | 1 | 5/60 | 6 |
| Adult | Brief Pain Inventory (BPI) | 24 | 1 | 13/60 | 5 |
| Adult | Patient Health Questionnaire (PHQ-8), Generalized Anxiety Disorder (GAD-7), CDC Health-Related Quality of Life (HRQoL-4) | 24 | 1 | 10/60 | 4 |
| Adult | CDC HRQoL-4 | 69 | 1 | 4/60 | 5 |
| Adult | CDC HRQoL-4 with activity limitation questions | 69 | 1 | 7/60 | 8 |
| Adult | Self-Rating Depression Scale (SDS) | 24 | 1 | 7/60 | 3 |
| Adult | Illness Impact | 69 | 1 | 3/60 | 3 |

| | | | | | |
|-----------|--|----|---|------|---|
| | Questionnaire | | | | |
| Adult | Saliva Data Collection Sheet | 69 | 1 | 5/60 | 6 |
| Adult | Orthostatic Grading Scale (OGS) | 69 | 1 | 5/60 | 6 |
| Adult | COMPOSITE Autonomic Symptom Score 31 (COMPASS-31) | 69 | 1 | 7/60 | 8 |
| Pediatric | CDC Symptom Inventory: For Baseline Subjects Pediatrics | 36 | 1 | 8/60 | 5 |
| Pediatric | CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics | 29 | 1 | 6/60 | 3 |
| Pediatric | SF-36 Health Survey | 64 | 1 | 5/60 | 5 |
| Pediatric | Multidimensional Fatigue Inventory (MFI-20) | 64 | 1 | 2/60 | 2 |
| Pediatric | Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions | 64 | 1 | 5/60 | 5 |
| Pediatric | PROMIS Pediatric Instruments (Fatigue & Pain) | 64 | 1 | 2/60 | 2 |
| Pediatric | Pediatric Pain Questionnaire (PPQ) | 64 | 1 | 7/60 | 8 |
| Pediatric | Visual Analogue Scale | 64 | 1 | 6/60 | 6 |
| Pediatric | Hospital Anxiety and Depression Scale | 64 | 1 | 5/60 | 5 |
| Pediatric | Pediatric Daytime Sleepiness Scale | 64 | 1 | 2/60 | 2 |

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|-----------|--|----|---|-------|---|
| Pediatric | Social Participation Form Pediatric | 64 | 1 | 7/60 | 8 |
| Pediatric | Sociability Form | 64 | 1 | 3/60 | 3 |
| Pediatric | Saliva Collection Form | 64 | 1 | 5/60 | 5 |
| Pediatric | CDC Symptom Inventory: For Baseline Subjects Pediatrics | 3 | 1 | 20/60 | 1 |
| Pediatric | CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics | 3 | 1 | 9/60 | 0 |
| Pediatric | SF-36 Health Survey | 3 | 1 | 9/60 | 0 |
| Pediatric | Multidimensional Fatigue Inventory (MFI-20) | 3 | 1 | 7/60 | 0 |
| Pediatric | Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions | 3 | 1 | 10/60 | 0 |
| Pediatric | PROMIS Pediatric Instruments (Fatigue & Pain) | 3 | 1 | 3/60 | 0 |
| Pediatric | Pediatric Pain Questionnaire (PPQ) | 3 | 1 | 15/60 | 1 |
| Pediatric | Visual Analogue Scale | 3 | 1 | 8/60 | 0 |
| Pediatric | Hospital Anxiety and Depression Scale | 3 | 1 | 7/60 | 0 |
| Pediatric | Pediatric Daytime Sleepiness Scale | 3 | 1 | 3/60 | 0 |
| Pediatric | Social Participation Form Pediatric | 3 | 1 | 10/60 | 0 |
| Pediatric | Sociability Form | 3 | 1 | 5/60 | 0 |

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|-----------|---|-----|---|-------|----|
| Pediatric | Saliva Collection Form | 3 | 1 | 5/60 | 0 |
| Adult | CogState Practice Section | 109 | 1 | 17/60 | 31 |
| Adult | CogState Baseline Section | 109 | 1 | 27/60 | 49 |
| Adult | WAIS IV DS F+B, TOPF | 109 | 1 | 10/60 | 18 |
| Adult | Exercise (Bike) Testing | 64 | 1 | 30/60 | 32 |
| Adult | CogState Time 1 Section | 109 | 1 | 22/60 | 40 |
| Adult | CogState Time 2 Section | 109 | 1 | 12/60 | 22 |
| Adult | CogState Time 3 Section | 109 | 1 | 12/60 | 22 |
| Adult | CogState Time 4 Section | 109 | 1 | 12/60 | 22 |
| Adult | Visual Analogue Scale for CFS Symptoms | 60 | 1 | 8/60 | 8 |
| Adult | EQ-5D-Y Health Questionnaire | 60 | 1 | 6/60 | 6 |
| Adult | PROMIS SF v1 - Physical Function | 60 | 1 | 5/60 | 5 |
| Adult | Physical Fitness and Exercise Activity Levels of Scale | 60 | 1 | 2/60 | 2 |
| Adult | International Physical Activity Questionnaire (Self-Administered Long Form) | 60 | 1 | 5/60 | 5 |
| Adult | Physical Activity Readiness Questionnaire | 60 | 1 | 5/60 | 5 |
| Adult | Visual Analogue Scale for CFS Symptoms | 49 | 1 | 8/60 | 6 |
| Adult | EQ-5D-Y Health Questionnaire | 49 | 1 | 6/60 | 5 |

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|-------|--|----|---|------|-----|
| Adult | PROMIS SF v1 - Physical Function | 49 | 1 | 5/60 | 4 |
| Adult | Physical Fitness and Exercise Activity Levels of Scale | 49 | 1 | 2/60 | 2 |
| Adult | International Physical Activity Questionnaire (Self- Administered Long Form) | 49 | 1 | 5/60 | 4 |
| Adult | Physical Activity Readiness Questionnaire | 49 | 1 | 5/60 | 4 |
| Total | | | | | 715 |

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