

**Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0920-1026)**

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**TITLE OF INFORMATION COLLECTION:**

Chronic Fatigue Syndrome: Symptoms from the Patient Perspective

**PURPOSE:**

Chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis (ME), is a complex illness affecting over one million U.S. adults [Jason et al. 1999; Reyes et al. 2003]. While severe and persistent fatigue is a key feature of the illness, patients also experience a number of other symptoms such as impaired concentration, muscle and joint pain, and post-exertional malaise (PEM). The multi-systemic and debilitating nature of the illness leads CFS patients to experience functional impairment which is comparable to that associated with other chronic conditions, such as heart disease, multiple sclerosis, cancer, diabetes, lung disease and rheumatoid arthritis [Komaroff et al. 1996; Nacul et al. 2011].

In February 2015, the Institute of Medicine (IOM) issued a report on CFS/ME that recommended revised diagnostic criteria and increased medical education to improve the care provided to ME/CFS patients. [IOM, 2015]. As a primary source of information and guidance materials for healthcare professionals, patients, and the public, the CDC CFS website, <http://www.cdc.gov/cfs/index.html>, provides information on causes of CFS, symptoms, diagnosis, and management. In 2011, CDC developed a Toolkit (both online and in print) for healthcare professionals to provide an easy-to-use resource for clinical care, however, with the publication of the IOM report, CDC was prompted to archive the Toolkit.

CDC seeks feedback from CFS patients about their symptoms and the effects that the illness has on functioning in order to revise educational materials, provide more accurate diagnostic guidance to clinicians and update the CDC website. The information collected from patients will be used to evaluate current CDC CFS educational materials, assist in revising and developing new materials and continuing medical education courses.

CDC will conduct 4 focus groups (Attachment 1: CFS Patient Perspective Focus Group Guide) and 12 interviews (Attachment 2: CFS Patient Perspective Interview Guide). The CFS focus groups will take place at Fieldwork facilities in Denver, Colorado (2 focus groups) and Orange County, California (2 focus groups). Fieldwork will use the verbiage from Attachment 3: CFS Patient Perspective Focus Group Recruitment Flyer to recruit for the CFS focus groups from their internal database. Specifically, Fieldwork will include the verbiage of Attachment 3 as an email and as posts to social media (Facebook and Twitter). In order to confirm participation in the focus groups, Fieldworks will screen the respondent (Attachment 5: CFS Patient Perspective Focus Group Screener). The screener was recommended to identify qualified participants and prevent habitual focus group participants from gaining access to the focus group (i.e. persons who participate in focus groups on a regular basis).

In addition to the focus groups, CDC will conduct 12 individual interviews with CFS patients in order to collect feedback about how patients perceive CFS. Interviews are being conducted with CFS patients who are unable to physically leave their residence due to effects of the illness. These patients will be recruited through CFS patient organizations using the verbiage of Attachment 4: CFS Patient Perspective Interview Recruitment Flyer. The focus group and interview questions ask patients about symptoms from the currently used 1994 Case Definition and additional symptoms recommended by the IOM report. CDC will ask open-ended questions to document patient's description of their symptoms and then use that terminology in revised educational materials. CDC will also ask CFS patients about what they expect from healthcare professionals when asked about their CFS symptoms. This information will assist guiding healthcare professionals in management of patients. Data obtained from these collections of information will be used to revise educational materials, provide more accurate diagnostic guidance to clinicians and update the CDC website.

**DESCRIPTION OF RESPONDENTS:**

Respondents are persons (male or female) who have received a CFS diagnosis from a physician and still have CFS. For the focus groups, the age range is 18-55 and for the individual interviews, the range is 18-70. The age range was broadened for the interviews as those are conducted at home and therefore reduce the travel burden for older persons with CFS).

**TYPE OF COLLECTION:** (Check one)

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|--|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input type="checkbox"/> Customer Satisfaction Survey                |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group                      |
| <input type="checkbox"/> Focus Group                                   | <input checked="" type="checkbox"/> Other: Focus group and interview |

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Dana Brimmer; dyv4@cdc.gov

To assist review, please provide answers to the following question:

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected?  Yes  No

2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974?  Yes  No
3. If Applicable, has a System or Records Notice been published?  Yes  No

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?  Yes  No

A \$50.00 money order will be given to the focus group participants to cover travel expenses and parking. Interview participants will not receive any gifts or payments as they will be interviewed over the telephone in their own homes.

**BURDEN HOURS**

Category of Respondent	No. of Respondents	Participation Time	Burden
Patient_Screener questionnaire	50	4/60	4
Patient_Focus groups	40	2 hours	80
Patient_Interviews	12	1.25 hours	15
<b>Totals</b>			

**FEDERAL COST:** The estimated annual cost to the Federal government is \$138,000\_\_\_\_\_

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?  Yes  No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Please see Attachment 6: CFS Patient Perspective Sampling Plan.

**Administration of the Instrument**

1. How will you collect the information? (Check all that apply)
  - Web-based or other forms of Social Media
  - Telephone
  - In-person
  - Mail
  - Other, Explain
2. Will interviewers or facilitators be used?  Yes  No

Attachments:

- Attachment 1: CFS Patient Perspective Focus Group Guide
- Attachment 2: CFS Patient Perspective Interview Guide
- Attachment 3: CFS Patient Perspective Focus Group Recruitment Flyer
- Attachment 4: CFS Patient Perspective Interview Recruitment Flyer
- Attachment 5: CFS Patient Perspective Focus Group Screener
- Attachment 6: CFS Patient Perspective Sampling Plan