**This CRF is used to support the Core DePaul Symptom Questionnaire (DSQ) PEM Subscale Instrument and is used in all studies.**

*For the following questions, we would like to know****how often you have had each symptom****and****how much each symptom has bothered you over the last 6 months****.*

*For each symptom please circle one number for frequency and one number for severity. Please fill the chart out from left to right.*

|  |  |  |
| --- | --- | --- |
| Symptom | Frequency  Throughout the past 6 months, how often have you had this symptom?  For each symptom listed below, circle a number from:  0 = none of the time  1 = a little of the time  2 = about half the time  3 = most of the time  4 = all of the time | Severity  Throughout the past 6 months, how much has this symptom bothered you?  For each symptom listed below, circle a number from:  0 = symptom not present  1 = mild  2 = moderate  3 = severe  4 = very severe |
| 1. Dead, heavy feeling after starting to exercise | 0 1 2 3 4 | 0 1 2 3 4 |
| 1. Next day soreness or fatigue after non-strenuous, everyday activities | 0 1 2 3 4 | 0 1 2 3 4 |
| 1. Mentally tired after the slightest effort | 0 1 2 3 4 | 0 1 2 3 4 |
| 1. Minimum exercise makes you physically tired | 0 1 2 3 4 | 0 1 2 3 4 |
| 1. Physically drained or sick after mild activity | 0 1 2 3 4 | 0 1 2 3 4 |

1. Was the DSQ PEM Threshold met?

No

Yes

1. What method was used to determine whether the study participant experiences PEM? (Please check all answers that apply.)

The 2-step DSQ PEM/researcher evaluation process (recommended)

Previously reported by a ME/CFS specialist

Previously reported by other medical provider who is not an ME/CFS specialist

Patient-reported - using DSQ PEM questions

Patient-reported - other sources

Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Does the study participant experience PEM?

No

Yes

Inconclusive

Not Evaluated

## GENERAL INSTRUCTIONS

## This CRF Module is used to support the Core DePaul Symptom Questionnaire (DSQ) PEM Subscale Instrument and is recommended as Core for all ME/CFS studies.

## SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* + Timeframe to assess symptoms: The severity and frequency of symptoms should be assessed over the last 6 months.
  + Scoring algorithm: A frequency of at least 2 and a severity of at least 2 on any *one* of the 5 questions on the DSQ PEM subscale indicates that PEM is present. If the study participant meets this threshold, the DSQ PEM Threshold is set to “Yes;” otherwise it is set to “No.” A frequency of 2 on one question and a severity of 2 on a separate question does not satisfy this threshold.
  + Guidance on “PEM Determination Method:”The standard method for evaluating the “Global PEM Determination” is a two step process in which the study participant responds to the DSQ PEM questions and the researcher than evaluates those responses in light of other information about the study participant to determine whether the study participant has PEM or not. In making this determination, the researcher or clinician will need to consider whether there are other conditions, such as overwork, that could result in a false positive DSQ PEM subscale response. On the other hand, the researcher or clinician should also consider whether the study participant responded negatively because, for instance, they carefully manage their energy expenditures with pacing to avoid episodes of PEM. In addition to asking questions about workload and pacing, the researcher may also ask what happens to the study participant if/when they engage in physical or mental activity and whether there are activities they avoid because it exacerbates symptoms. In addition to their own examination of the study participant, the researcher may also consider information from sources like medical records but these should be carefully considered, as they might not reflect an accurate understanding of the nature of PEM.

While the above method should be used in all studies, there may certain types of studies, such as patient surveys or studies of existing samples in which it is not possible to use this two-step method. In those limited instances, the researcher may be able to use information from other sources, such as patient reports and medical records as the basis of the Global PEM Determination. These other choices, particularly self-report and reports by other medical providers, are not recommended because these reports of PEM have not been verified.

* + The following choices are provided to capture the method used to determine PEM:
* The 2-step DSQ PEM/researcher evaluation process (recommended)
* Previously reported by ME/CFS Specialist
* Previously reported by other Medical Provider who is not an ME/CFS specialist
* Patient reported - using DSQ PEM questions
* Patient-reported – other sources
* Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Multiple choices can be selected if appropriate. The first choice should only be selected when the two-step process described above is used.

* + Guidance on “Global PEM Determination:” Regardless of the method used as described in the previous section, the presence or absence of PEM is captured in this field using one of the following choices:
    - * Yes
      * No
      * Inconclusive
      * Not Evaluated

## REFERENCES

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