Instructions: This CRF contains questions which should be completed for all ME/CFS studies. The questions regarding treatment for sleep issues and the DSQ sleep items are classified as Core. The NHANES questions are classified as Exploratory.

\* Is the study participant receiving any treatment for sleep issues? (e.g., supplements, medication, behavioral measures, etc.)?

☐ Yes (complete medication log)

☐ No

☐ Not sure

*Depending on the purpose of the study, researchers may choose to use only the DSQ, or both instruments.*

\* DSQ sleep items1:

For the following questions (19-24), 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.

|  |  |  |
| --- | --- | --- |
|  | *Frequency* | *Severity* |
| **Symptoms** | 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 time1 = a little of the time2 = about half the time3 = most of the time4 = all of the time | Throughout the **past 6 months**, **how much** has this symptom bothered you?For each symptom listed below, circle a number from:0 = symptom not present1 = mild2 = moderate3 = severe4 = very severe |
| 19) Feeling unrefreshed after you wake up in the morning | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |
| 20) Need to nap daily | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |
| 21) Problems falling asleep | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |
| 22) Problems staying asleep | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |
| 23) Waking up early in the morning (e.g. 3am) | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |
| 24) Sleep during day and stay awake during night | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 | ☐ 0   ☐ 1   ☐ 2 ☐ 3  ☐ 4 |

\*\*NHANES Questions2:

1. Do you have trouble falling asleep?

☐ Never

☐ Rarely (once a month)

☐ Sometimes (2-4 times a month)

☐ Often (5-15 times a month)

☐ Almost always (16-30 times a month)

1. Do you wake up during the night and have trouble getting back to sleep?

☐ Never

☐ Rarely (once a month)

☐ Sometimes (2-4 times a month)

☐ Often (5-15 times a month)

☐ Almost always (16-30 times a month)

1. Do you wake up too early in the morning and **are unable** to get back to sleep (Early Morning Awakening -EMA)?”

☐ Never

☐ Rarely (once a month)

☐ Sometimes (2-4 times a month)

☐ Often (5-15 times a month)

☐ Almost always (16-30 times a month)

1. In the past month, how often did you feel unrested during the day, no matter how many hours of sleep you have had?”

☐ Never

☐ Rarely (once a month)

☐ Sometimes (2-4 times a month)

☐ Often (5-15 times a month)

☐ Almost always (16-30 times a month)

## General Instructions

This form contains data elements that are collected for all ME/CFS studies. The question regarding treatment for sleep disorders and the DSQ sleep items data elements on this CRF are classified as Core. The NHANES questions data elements on this CRF are classified as Exploratory.

\*Element is classified as Core

\*\*Element is classified as Exploratory

**Note**: Sleep disturbances are experienced by over 90% of people affected by ME/CFS and consequently are included as part of the criteria for most ME/CFS case definitions. Yet, most studies report only if individual study participants qualify for a specific case definition and often do not specify if  individuals experience sleep disturbances or the type of sleep disturbance.  To assure and standardize reporting across studies, we developed a CRF to  assess sleep issues in study participants enrolled in ANY ME/CFS study.

Since the DePaul Symptom Questionnaire (DSQ) was designed for ME/CFS populations, has been used in multiple ME/CFS studies, and is brief, we chose to include DSQ sleep items as part of this CRF. The DSQ has its shortcomings. The DSQ sleep items have not been validated separately from the whole DSQ nor tested against objective sleep outcomes. The wording of final item in the DSQ may be problematic for adolescents in particular, as they may not be ‘bothered’ by sleeping all day and staying awake all night but their families may. They may not be able to quantify day night phase shift if the question asks only about ‘all day’. Preferred wording may be ‘during’ the night and ‘during’ the day. This reversal of sleep times also affects adults.

We also chose to include 4 items related to sleep from the 2008 and 2009 National Health and Nutrition Examination (NHANES) survey. The NHANES surveys are an ongoing series of studies conducted for the last 5 decades by the US Centers for Disease Control and Prevention to track and monitor the nutritional and health status of adult and pediatric US residents. In one recent study [reference below], study participants who endorsed problems with unrefreshing sleep on the NHANES were shown to be different from participants endorsing problems with getting or staying asleep. Since few sleep instruments are short, query about unrefreshing sleep specifically, and are able to show differences between sleep disturbance types, we chose to include items from the NHANES. The NHANES survey was not designed for and has not been tested specifically in ME/CFS patients. Nevertheless, it can yield useful information. It might be particularly suitable for studies where sleep issues in ME/CFS patients are to be compared to healthy or other sick populations whereas the DSQ might be more suitable for studies focused only on ME/CFS subjects. The DSQ has hardly been tested and used outside of the ME/CFS field and consequently might not be as useful for the former purpose. Depending on their study’s goals, researchers may choose to use only the DSQ or both instruments. Researchers may apply to the CDC for access to NHANES survey results.

Specific Instructions

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

References

1. <http://condor.depaul.edu/ljason/cfs/>
2. <https://www.cdc.gov/nchs/nhanes/about_nhanes.htm>
3. Zhang J, Lamers F, Hickie IB, He J-P, Feig E, Merikangas KR. Differentiating Nonrestorative Sleep from Nocturnal Insomnia Symptoms: Demographic, Clinical, Inflammatory, and Functional Correlates. *Sleep*. 2013;36(5):671-679. doi:10.5665/sleep.2624. ([LINK](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624821/#B17))
4. Ohayon MM. Prevalence and Correlates of Nonrestorative Sleep Complaints. *Arch Intern Med.* 2005;165(1):35–41. doi:10.1001/archinte.165.1.35 ([LINK](http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486352))