



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

### NIH Resources

The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

Disease/Domain;Sub-domain	Recommendations
<b>Participant/Subject Characteristics;</b> Demographics:	<b>Core:</b> General Core <b>Supplemental-Highly Recommended:</b> General Core <b>Supplemental:</b> Demographics <b>Exploratory:</b> None
<b>Participant/Subject Characteristics;</b> Social Status:	<b>Core:</b> None <b>Supplemental-Highly Recommended:</b> Adult Employment and Education History <b>Supplemental:</b> None <b>Exploratory:</b> None
<b>Participant History and Family History;</b> General Health History:	<b>Core:</b> Past and Current Illnesses, Medical History - Immune Module <b>Supplemental-Highly Recommended:</b> Medical History - Immune Module, Family Health History <b>Supplemental:</b> Reproductive and Hormonal History <b>Exploratory:</b> Medical History - Immune Module, Exposure History
<b>Disease/Injury Related Events;</b> History of Disease/Injury Event:	<b>Core:</b> DePaul Symptom Questionnaire (DSQ) or ME/CFS Symptom Checklist <b>Supplemental-Highly Recommended:</b> None <b>Supplemental:</b> DSQ-Pediatric Screening Questionnaire (DSQ-PSQ), Fatigue Visual Analog Scale, Neuroendocrine/Hypothalamic Symptoms <b>Exploratory:</b> None



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

Disease/Domain;Sub-domain	Recommendations
<b>Assessments and Examinations;</b> Physical/Neurological Examination:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Neurological Exam, Physical Examination, Physical Exam - Immune Module, Pain Assessment, Beighton Score</p> <p><b>Supplemental:</b> Neurological Exam, Polysomnography (PSG) for ME/CFS, Pain Assessment</p> <p><b>Exploratory:</b> Neurological Exam, Grip Strength Fatigue</p>
<b>Assessments and Examinations;</b> Post-Exertional Malaise:	<p><b>Core:</b> Core PEM Assessment Questionnaire, Guidance for Core PEM Assessment</p> <p><b>Supplemental-Highly Recommended:</b> PEM-Focused Studies Questionnaire</p> <p><b>Supplemental:</b> Guidance for PEM-Focused Studies</p> <p><b>Exploratory:</b> PEM-Focused Studies Questionnaire</p>
<b>Assessments and Examinations;</b> Exercise Physiology:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Cardiopulmonary Exercise Testing (CPET)</p> <p><b>Exploratory:</b> None</p>
<b>Assessments and Examinations;</b> Autonomic:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Composite Autonomic Symptom Scale, Passive Standing Test Protocol</p> <p><b>Supplemental:</b> None</p> <p><b>Exploratory:</b> Modified Orthostatic Symptom Grading Scale</p>
<b>Assessments and Examinations;</b> Laboratory Tests and Biospecimens/Biomarkers:	<p><b>Core:</b> Neuroendocrine Labs</p> <p><b>Supplemental-Highly Recommended:</b> Laboratory Tests - Immune Module, Biomarker-Related Sample and Collection Questions</p> <p><b>Supplemental:</b> Laboratory Test Results, Laboratory Tests - Immune Module, Neuroendocrine Labs, Biomarker-Related Sample and Collection Questions, Biomarkers Guidelines, Biomarkers Reference Table</p> <p><b>Exploratory:</b> Neuroendocrine Labs</p>



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

Disease/Domain;Sub-domain	Recommendations
<b>Assessments and Examinations;</b> Imaging Diagnostics:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Magnetic Resonance Imaging (MRI), Functional Magnetic Resonance Imaging (fMRI), Diffusion Tensor Imaging (DTI), Magnetic Resonance Spectroscopy (MRS), Positron Emission Tomography (PET), Magnetoencephalography (MEG), Non-Quantitative Electroencephalography (EEG), Quantitative Electroencephalography (qEEG), Low Resolution Electromagnetic Tomography (LORETA)</p> <p><b>Supplemental:</b> Special Imaging Considerations, Suggested Parameters for Common Magnetic Resonance Imaging (MRI) Scans, ME/CFS Functional Imaging Task Summaries</p> <p><b>Exploratory:</b> None</p>
<b>Treatment/Intervention Data;</b> Drugs:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Medications/Other Treatments</p> <p><b>Supplemental:</b> None</p> <p><b>Exploratory:</b> None</p>
<b>Outcomes and Endpoints</b>	
<b>Outcomes and Endpoints;</b> Academic Achievement:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Word Reading Subtest of the Wide Range Achievement Test (WRAT-4)</p> <p><b>Supplemental:</b> None</p> <p><b>Exploratory:</b> None</p>
<b>Outcomes and Endpoints;</b> Activities of Daily Living/Performance:	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Fatigue/Activity Record and Diary, Modifiable Activity Questionnaire (MAQ)</p> <p><b>Exploratory:</b> Physical Functioning and Activities of Daily Living</p>



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

Disease/Domain;Sub-domain	Recommendations
<p><b>Outcomes and Endpoints;</b> Attention/Information Processing:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Paced Auditory Serial Addition Test (PASAT), Stroop Test, Children's Paced Auditory Serial Addition Task (ChiPASAT)</p> <p><b>Supplemental:</b> Automated Neuropsychological Assessment Metrics (ANAM), Test of Variables of Attention (TOVA)</p> <p><b>Exploratory:</b> Deary-Liewald Reaction Time Task</p>
<p><b>Outcomes and Endpoints;</b> Emotional/Behavioral:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Beck Anxiety Inventory (BAI), Beck Depression Inventory II (BDI-II)</p> <p><b>Supplemental:</b> Center for Epidemiologic Studies-Depression Scale (CES-D), State-Trait Anxiety Inventory (STAI)</p> <p><b>Exploratory:</b> Kiddie-Schedule for Affective Disorders and Schizophrenia for School-Aged Children-Present and Lifetime Version (K-SADS-PL)</p>
<p><b>Outcomes and Endpoints;</b> Executive Functioning:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Delis-Kaplan Executive Function System (D-KEFS)</p> <p><b>Supplemental:</b> NIH Toolbox Cognitive Battery, Cogstate Tests, Cambridge Neuropsychological Test Automated Battery (CANTAB)</p> <p><b>Exploratory:</b> None</p>
<p><b>Outcomes and Endpoints;</b> Fatigue:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Fatigue Severity Scale (FSS)</p> <p><b>Supplemental:</b> Checklist for Individual Strength - Fatigue (CIS), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue, Wood Mental Fatigue Inventory, Pediatric Quality of Life Inventory, Multidimensional Fatigue Scale</p> <p><b>Exploratory:</b> Neuro-QoL Adult Bank – Fatigue, Modified Fatigue Impact Scale (MFIS), Multidimensional Fatigue Inventory (MFI), PROMIS Fatigue Short Form</p>



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

Disease/Domain;Sub-domain	Recommendations
<p><b>Outcomes and Endpoints;</b> Intellectual Functioning:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Edinburgh Handedness Inventory</p> <p><b>Supplemental:</b> North American Adult Reading Test (NAART), Test of Premorbid Functioning (TOPF), Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV)</p> <p><b>Exploratory:</b> Wechsler Abbreviated Scale of Intelligence - Second Edition (WASI-II), Woodcock-Johnson III Test of Cognitive Abilities, Wechsler Intelligence Scale for Children-Fifth Edition (WISC-V)</p>
<p><b>Outcomes and Endpoints;</b> Memory:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> California Verbal Learning Test - Second Edition (CVLT-II), Rey-Osterrieth Complex Figure Test (ROCF), California Verbal Learning Test - Children (CVLT-C)</p> <p><b>Supplemental:</b> Wechsler Memory Scale IV (WMS-IV), Children's Memory Scale (CMS)</p> <p><b>Exploratory:</b> None</p>
<p><b>Outcomes and Endpoints;</b> Motor Function:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> None</p> <p><b>Supplemental:</b> None</p> <p><b>Exploratory:</b> Speeded Tapping Test</p>
<p><b>Outcomes and Endpoints;</b> Pain:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Brief Pain Inventory (Short Form) (BPI), Revised Fibromyalgia Impact Questionnaire (FIQR), McGill Pain Questionnaire (MPQ), Faces Pain Scale - Revised (FPS-R)</p> <p><b>Supplemental:</b> Pain Frequency-Severity-Duration Scale (PFSD)</p> <p><b>Exploratory:</b> Neuropathic Pain Symptom Inventory, PROMIS Pain Behavior Short Form, PROMIS Pain Interference Short Form</p>



## Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Highlight Summary Document

Disease/Domain;Sub-domain	Recommendations
<p><b>Outcomes and Endpoints;</b> Quality of Life/Patient Reported Outcomes:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Child Health Questionnaire</p> <p><b>Supplemental:</b> Mental Fatigue Scale (MFS), Short Form 36-Item Health Survey (SF-36), Functional Disability Inventory-Child and Adolescent Form (FDI), Functional Disability Inventory-Parent Form (FDI)</p> <p><b>Exploratory:</b> Bell CFIDS Disability Scale, EuroQoL-5 Dimension Questionnaire (EQ-5D), Health Related Quality of Life (HRQOL-14), Karnofsky Performance Scale, World Health Organization Disability Assessment Schedule (WHODAS)</p>
<p><b>Outcomes and Endpoints;</b> Sleep:</p>	<p><b>Core:</b> Sleep Questions for All Studies</p> <p><b>Supplemental-Highly Recommended:</b> Sleep Focused Study Questionnaire, Sleep Assessment Questionnaire – Moldofsky</p> <p><b>Supplemental:</b> Sleep Focused Study Questionnaire, Pittsburgh Sleep Quality Index, Stanford Sleepiness Scale, Sleep Disorders Screening Checklist, Holland Sleep Disorders Questionnaire (HSDQ)</p> <p><b>Exploratory:</b> Sleep Questions for All Studies, Epworth Sleepiness Scale - Children's Version, Nonrestorative Sleep Scale (NRSS), Global Sleep Assessment Questionnaire (GSAQ), Restorative Sleep Questionnaire (RSQ), Adolescent Sleep Hygiene Scale (ASHS)</p>
<p><b>Outcomes and Endpoints;</b> Visual-Spatial Processing:</p>	<p><b>Core:</b> None</p> <p><b>Supplemental-Highly Recommended:</b> Rey-Osterrieth Complex Figure Test (ROCF)</p> <p><b>Supplemental:</b> None</p> <p><b>Exploratory:</b> None</p>