Appendix 1. Passive Standing Test Form

The attached form is based on the passive standing test used in the Pediatric Chronic Fatigue Clinic at Johns Hopkins Children's Center during the study period. With minor modifications, it is now available from the National Institute of Neurological Disorders and Stroke Common Data Elements website:

https://www.commondataelements.ninds.nih.gov/

Grinnon ST, Miller K, Marler JR, Lu Y, Stout A, Odenkirchen J, Kunitz S. National Institute of Neurological Disorders and Stroke Common Data Element Project - approach and methods. Clin Trials. 2012;9:322-9. Epub 2012 Feb27. PubMed PMID: 22371630

Passive Standing Test Protocol

[Study Name/ID pre-filled]

Site Name:
Subject ID:

Instructions: The examiner will complete this standing test data sheet.
Date of Test:

List medications taken in last 2 weeks:

	Heart Rate	Blood Pressure	Comments/Symptom Ratings*
SUPINE			
1 min			
2 min			
3 min			
4 min			
5 min			
STANDING			
1 min			
2 min			
3 min			
4 min			
5 min			
6 min			
7 min			
8 min			
9 min			
10 min			
SUPINE			
1 min			
2 min			

*Abbreviations for Orthostatic Signs and Symptoms:

ACRO Acrocyanosis
COG Cognitive difficulties
FTG Fatigue
HA Headache
HOT Warmth/hot flash
LH Lightheadedness
NAU Nausea
PAL Pallor
PN Muscle pain/ache
SOB trouble breathing
SW Sweating

Passive Standing Test Protocol CRF Module Instructions

[Study Name/ID pre-filled]

Site Name:
Subject ID:

General Instructions

The following is a modification of the passive standing test (*Hyatt KH, Jacobson LB, Schneider VS. Comparison of 70°tilt, LBNP, and passive standing as measures of orthostatic tolerance. Aviat Space Environ Med 1975;46: 801-808*). The standing test begins with the subject lying supine, with shoes and socks removed, with an automated BP cuff set to record BP and HR at 1-minute intervals. The subject is supine for 5 minutes. The baseline heart rate (HR) and blood pressure (BP) are measured and recorded each minute for 5 minutes' supine. At the 4-5 minute point, record the intensity of the patient's current symptoms (on a 0-10 scale). The patient is then instructed to stand, with the heels 2-6 inches away from the wall, and with the upper back leaning against the wall in a comfortable but **motionless position** for a maximum of 10 minutes. Each minute, HR and BP are recorded and the patient is asked about symptoms, for a maximum of 10 minutes upright. At the conclusion of the standing period, the patient is instructed to lie supine again, while the BP, HR and symptom intensity are measured for a further 2 minutes.

Specific instructions are as follows:

> "We'd like you to stand as still as possible for up to 10 minutes. During the standing test, you must be as motionless as possible in order to get an accurate result. Therefore, try not to wiggle your toes or fingers, scratch your nose, or move your arms or legs. We will monitor for any movements and will remind you not to move or wiggle. We want you to tell us if you are feeling anything different or uncomfortable during the test. Be as specific as possible. **We need to know if you feel you can't stay standing any longer, and if this is the case you can sit down.** It is not necessary to remain standing for the entire 10 minutes, but we'd like to measure how long you can do this. Each minute we will check your blood pressure and heart rate with an automatic measuring device."

COMMENTS:

Medication taken should be documented in the Medication Log CRF. Decisions about whether to allow study participants to remain on vasoactive medications are specific to the study question. In studies that examine the prevalence of orthostatic intolerance among those with ME/CFS, study participants would stop all vasoactive medications before the study. However, stopping medications is not always safe (for example, discontinuing an SSRI/SNRI medication could cause harm). Conversely, a study examining improvement in quality of life and orthostatic tolerance in response to treatment would need to allow participants to remain on medications during testing.

If the subject reports any changes in their ME/CFS symptoms or emergence of orthostatic signs and symptoms (see bolded **abbreviations above)**, list these in the comments column along with the corresponding time recorded for the BP and HR. The comment section should note the changes in symptom severity on a 0-10 scale, and grade the physical sign of acrocyanosis as absent, mild, moderate, or severe. The comments should note if and when the subject had to sit down before the completion of 10 minutes upright, and, if so, mention whether the final upright BP was performed sitting or standing. The reason for stopping should be noted in the Comments section.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module. All the data elements on this CRF are Supplemental-Highly Recommended.

- Date of test – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times (Please click here for the International Organization for Standardization website). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).

Passive Standing Test Protocol CRF Module Instructions

[Study Name/ID pre-filled]

Site Name:
Subject ID:

References

Hyatt KH, Jacobson LB, Schneider VS. Comparison of 70°tilt, LBNP, and passive standing as measures of orthostatic tolerance. Aviat Space Environ Med 1975;46: 801-808