Pre Test Comments:  
Post Test Comments:  
Last Calibration:

Start Exercise:

(Warm up at 5 watts for 2 min, then 10 watts for 2 min and 15 watts for 5 min (absolute). If heart rate is less than 130 then increase by 10 watts every 2 minutes until Peak. Otherwise, increase by 5 watts every 2 minutes until Peak.)

Start Recovery:

| This cell intentionally left blank | Rest | Submaximal (15 Watts x 5 min)  Absolute Trial | VAT (optional) | V02 Peak | Prediction | AT / VO2 Peak (%) | VO2 Peak/  Prediction (%) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Time (min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Datum not collected | Datum not collected |
| Ex Time (min) | Datum not collected | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Datum not collected | Datum not collected |
| **WORK** | | | | | | | |
| Work (Watts) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| Speed (RPM) | Datum not collected | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| **VENTILATION** | | | | | | | |
| Vt BTPS (L) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| RR (br/min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| VE BTPS (L/min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| **O2 CONSUMPTION** | | | | | | | |
| VO2 (mL/kg/min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| VO2 (mL/min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| VCO2 (mL/min) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| RER | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| **CARDIAC** | | | | | | | |
| Heart Rate (BPM) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| VO2/HR (mL/beat) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| **V/Q** | | | | | | | |
| VE/VCO2 | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| VE/VO2 | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| PETCO2 (mmHg) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| PETO2 (mmHg) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| This row intentionally left blank | | | | | | | |
| sysBP (mmHg) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| diaBP (mmHg) | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| RatePrsPd SBP\*HR/100 | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| Borg - breathlessness | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |
| Borg - legs | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Datum not collected | Data to be collected by site | Datum not collected |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Time  (min) | Work  (Watts) | VO2  (mL/min) | VO2  (mL/kg/min) | VCO2 (mL/min) | RER | Heart Rate (BPM) | VE | BTPS (L/min) | RR (br/min) | SpO2(%) | sysBP (mmHg) | diaBP (mmHg) | Borg PE |
| Start Ex | | | | | | | | | | | | | |
| Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| AT | | | | | | | | | | | | | |
| Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |
| Start R | | | | | | | | | | | | | |
| Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site | Data to be collected by site |

**Exercise Recovery Questionnaire**

Study ID:

Date of Exercise Tests:

1. How did the participant feel following the first exercise test?   
2. Describe how the participant felt the day after the first exercise test.   
3. How did the participant feel following the second exercise test?   
4. Describe how participant felt the day after the second exercise test.   
5. How long did it take the participant to recover from the exercise tests? Circle the appropriate time…(in days)  
less than 1 2 3 4 5 6 7 still not recovered  
Comments:   
6. Describe symptoms, if any, experienced after the exercise tests.

Recorder Signature: Date:

## GENERAL INSTRUCTIONS

This CRF contains data that would be collected for a staged exercise tolerance test as part of a mitochondrial disease study. Standardized methodology should be used for employing CPET.

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease clinical studies to collect). All of the data elements are classified as Supplemental – Highly Recommended (i.e., essential information for specified conditions, study types, or designs) and should be collected if studies of the impact of an intervention on mitochondrial disease patient mobility and physiology are performed. Testing can be completed in both Adult and Pediatric populations over the age of 8.

Please see the Data Dictionary for element classifications.

## SPECIFIC INSTRUCTIONS

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

* Staged exercise tolerance test – 5 watts for 2 min, 10 watts for 2 min, 15 watts for 5 min (absolute). If heart rate is less than 130 then increase by 10 watts every 2 minutes until Peak. Otherwise, increase by 5 watts every 2 minutes until Peak.
* V02 Peak – If participant cannot complete submaximal test, indicate time at exhaustion and record as VO2 Peak
* Prediction – Prediction formula used to be determined by the study.
* Borg scale – The scale is mainly validated in older healthy children and adults, but the clinician can determine if administration is appropriate based on the participant’s cognitive ability to understand the scale.

## REFERENCES

American College of Sport’s Medicine. ACSM’s Guidelines for Exercise Testing and Prescription 9th Ed.  Philadelphia, PA. Wolters Kluwer/Lippincott Williams & Wilkins;2014.

American Thoracic Society; American College of Chest Physicians. ATS/ACCP Statement on cardiopulmonary exercise testing. Am J Respir Crit Care Med. 2003 Jan 15;167(2):211-77. Erratum in: Am J Respir Crit Care Med. 2003 May 15;1451-2.

Balady GJ, Arena R, Sietsema K, Myers J, Coke L, Fletcher GF, Forman D, Franklin B, Guazzi M, Gulati M, Keteyian SJ, Lavie CJ, Macko R, Mancini D, Milani RV; American Heart Association Exercise, Cardiac Rehabilitation, and Prevention Committee of the Council on Clinical Cardiology; Council on Epidemiology and Prevention; Council on Peripheral Vascular Disease; Interdisciplinary Council on Quality of Care and Outcomes Research. Clinician's Guide to cardiopulmonary exercise testing in adults: a scientific statement from the American Heart Association. Circulation. 2010 Jul 13;122(2):191-225.

Forman DE, Myers J, Lavie CJ, Guazzi M, Celli B, Arena R. Cardiopulmonary exercise testing: relevant but underused. Postgrad Med. 2010 Nov;122(6):68-86.

Gibbons RJ, Balady GJ, Bricker JT, Chaitman BR, Fletcher GF, Froelicher VF, Mark DB, McCallister BD, Mooss AN, O'Reilly MG, Winters WL, Gibbons RJ, Antman EM, Alpert JS, Faxon DP, Fuster V, Gregoratos G, Hiratzka LF, Jacobs AK, Russell RO, Smith SC; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Committee to Update the 1997 Exercise Testing Guidelines. ACC/AHA 2002 guideline update for exercise testing: summary article. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1997 Exercise Testing Guidelines). J Am Coll Cardiol. 2002 Oct 16;40(8):1531-40. Erratum in: J Am Coll Cardiol. 2006 Oct 17;48(8):1731.

Guazzi M, Adams V, Conraads V, Halle M, Mezzani A, Vanhees L, Arena R, Fletcher GF, Forman DE, Kitzman DW, Lavie CJ, Myers J; European Association for Cardiovascular Prevention & Rehabilitation; American Heart Association. EACPR/AHA Scientific Statement. Clinical recommendations for cardiopulmonary exercise testing data assessment in specific patient populations. Circulation. 2012 Oct 30;126(18):2261-74.

Pescatello LS, Arena R, Riebe D, Thompson PD. ACSM's guidelines for exercise testing and prescription. Philadelphia: Lippincott Williams & Wilkins; 2017.

Wasserman K, Hansen J, Sue D, Stringer W, Whipp B. Principles of exercise testing and interpretation: including pathophysiology and clinical applications. Philadelphia, PA: Wolters Kluwer/Lippincott Williams & Wilkins;2012.