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.

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