CKiD CPET CRF & CHECKLIST

DEMOGRAPHICS

Site ID #: _____	Date of Birth:	Age (years):	Weight (kg):	Height (cm):
CKiD ID: _____	_____	_____	_____	_____

Sex at birth: □ Female □ Male	Race: □ White □ Black □ Other **Race is required to calculate percent predicted VO2 for cycle ergometer.	Height >132cm? □ Yes (Continue) □ No (Do not continue)

Calculated Minute-Work rate (watts/stage):

_____

Use calculation: Watts = (Weight(kg) x 3) / 10

NOTE: Minute-work rate is capped at 30 W. If a participant has a calculated minute-work rate >30 W based on their weight, they will be assigned a minute-work rate of no greater than 30 W.

Exercise physiologists may use their discretion to deviate from the weight-based calculation of work rate by ±25%.

Was the calculated minute-work rate deviated from?

□ No □ Yes - Why?:

PRE-PARTICIPANT PREP

Follow your standard exercise lab procedures to prepare for cycle CPET.

□ Calibrate Metabolic Cart as per manufacturer recommendations

□ Set the metabolic cart display for 10-second averaging.

PARTICIPANT PREP

Prepare the participant for a cycle CPET following your standard exercise lab procedures.

□ Thoroughly explain testing procedures to participant.

□ Ensure the participant understands that PEAK INTENSITY IS REQUIRED, EXERCISE TO VOLITIONAL FATIGUE

□ Describe the participant is responsible for maintaining a 70-90 RPM pedal speed.

PRETEST

□ Perform ECG prep and place the participant in a seated, resting position. Participant should be seated and resting for at least 3-minutes prior to collection of pretest.

□ Print resting ECG once heart rate has stabilized. Ensure quality ECG to mitigate artifact.	**Baseline Heart Rate (bpm):** _____

□ Perform manual blood pressure (right arm) unless contraindicated. – If contraindicated in right arm take in left arm	**Baseline BP (mmHg):** _____/_____	□ Right arm □ Left am

□ Place oximeter probe on participant and obtain resting SpO2. - If a finger oximeter is being used the probe should not be placed on the same limb as the blood pressure is being obtained.	**Baseline SpO2 (%):** _____

□ If using mask over mouthpiece: While seated measure participant face (length in mm) for VO2 mask size. • Measure at least twice. • Use the average measurement to determine mask size.	**Face size (mm):** **1st measurement:** _____mm **2nd measurement:** _____mm **Do measurements differ by >4mm?** □ No (record average measurement below) □ Yes - **3rd measurement:** _____mm **Average measurement (mm):** _____mm	**Mask Size:** □ Child mask □ Petite □ Extra Small □ Small □ Medium

□ Provide participant instructions specific to the VO2 assessment (avoid talking/use non-verbal communication while collecting oxygen consumption).

□ Equip participant with VO2 mask or mouthpiece and headgear. Check that mask/mouthpiece has adequate seal without leaks.

□ Transition the participant from seated to standing position. □ Record highest orthostatic heart rate on CPET CRF prior to mounting the cycle.	**Highest orthostatic (sit-stand) Heart Rate (bpm):** _____

□ Guide participant to mount cycle ergometer.

□ Adjust the seat height such that the participant has only a slight bend in the knee when the leg is fully extended at the bottom of the pedal stroke.

□ Strap the participant's feet tightly into the pedals.

□ Adjust handlebars to the participant's preference.

□ Attach the metabolic system to the mask/mouthpiece (if applicable).

CPET EXERCISE TEST

□ Start 3-minutes of resting oxygen consumption.

- Instruct the participant to breathe normally and relax.

□ Ensure that the beginning and end of the 3-minute resting data collection is marked/timestamped the in the metabolic system.

□ Following 3-minute resting data collection - **START EXERCISE**

- Refer to the *Exercise Protocol Table*

TERMINATE THE TEST IF ANY SAFETY CONCERNS ARE NOTED AS PER SECTION 44.6.1 OF THE MOP

EXERCISE PROTOCOL TABLE

Enter test data in the CPET system and the white cells of this CRF. If the cell is blacked out, the data is not required for that stage.

Minute-Work Rate = _____ Watts

Stage	Duration (min)	Cumulative Time (min)	Test Variables			Minute Work Rate (MWR)	Cadence	Stages: Completed (✓) Partially Completed (-) (See MOP for detailed definitions)
			Heart Rate (BPM)	Blood Pressure (mmHg)	SpO2 (%)			
E1	3:00	0:00 – 2:59				0 W	Aim to maintain a range of 70-90 rpm **Permitted to have cadence >90 rpm during end of test sprint.	
E2	1:00	3:00 – 3:59						
E3	1:00	4:00 – 4:59						
E4	1:00	5:00 – 5:59						
E5	1:00	6:00 – 6:59						
E6	1:00	7:00 – 7:59						
E7	1:00	8:00 – 8:59						
E8	1:00	9:00 – 9:59		◊				
E9	1:00	10:00 – 10:59			◊			
E10	1:00	11:00 – 11:59						
E11	1:00	12:00 – 12:59		◊				
E12	1:00	13:00 – 13:59			◊			
E13	1:00	14:00 – 14:59						
E14	1:00	15:00 – 15:59		◊				

** If the exercise test surpasses 16 minutes, please continue to record data on your ECG/metabolic system and transfer to the Redcap following the test **

Highest peak heart rate observed: _____ bpm

Highest peak blood pressure observed: _____/_____ mmHg

Sprint performed at/near peak?

□ Yes □ No - Why:

Reason for Test Termination: □ Volitional fatigue (peak exertion). □ Administrator discretion. □ Participant request (early termination). □ Safety Concern. □ Other - Explain:

Abbreviations: min = Minutes; MWR = Minute Work Rate; W = Watts; HR = Heart rate; BP = Systolic and diastolic blood pressure; SpO2 = Arterial oxygen saturation. ◊ = Acquire if tolerated by the participant

EXERCISE RECOVERY PROTOCOL TABLE

Enter test data in the CPET system and the white cells of this CRF. If the cell is blacked out, the data is not required for that stage.

Stage	Duration (min)	Cumulative Time (min)	Test Variables			Procedures
			Heart Rate (BPM)	Blood Pressure (mmHg)	SpO2 (%)	
R1	1:00	0:00 – 0:59				Continue to collect VO2. Recovery pedaling (MWR = 0-10 W; Cadence = ~30 rpm)
R2	1:00	1:00 – 1:59				
R3	1:00	2:00 – 2:59				Cease pedaling (0 rpm) but remain seated on cycle. Continue to collect VO2 until the end of the stage.
R4	1:00	3:00 – 3:59				Stop VO2 data collection. Remove the metabolic mask or mouthpiece from the participant. Transition participant off the cycle ergometer to a seated position in a nearby chair.
R5	1:00	4:00 – 4:59				Continue monitoring the participant while in seated recovery
R6	1:00	5:00 – 5:59				
R7	1:00	6:00 – 6:59				
R8	1:00	7:00 – 7:59				

Abbreviations: min = Minutes; MWR = Minute Work Rate; W = Watts; HR = Heart rate; BP = Systolic and diastolic blood pressure; SpO2 = Arterial oxygen saturation.

General Comments/Notes:

□ Disconnect all CPET equipment/supplies from participant (O2 sat probe/BP cuff).

POST CPET PROCEDURES

□ Using 10-second averaging, print the CPET test report and summary report from CPET system. CPET report will be stored with the participant's local study materials.

□ Physical ECG tracings and ECG summary report will be stored with the participant's local study materials.

□ Using your exercise lab's standard procedure for reviewing exercise tests, review ECG tracings and other test data for safety concerns that were not observed during the exercise test and **complete the Safety Concern Checklist.**

- Notify the PI & coordinator of any safety concerns if applicable.

□ Export CPET Spreadsheet in .csv or .xml or .xlsx excel format & save on desktop.

- The CPET spreadsheet export should utilize 10-second averaging.
- The spreadsheet should be formatted as follows (mimic the order of the columns):

Overall Test Time (min:sec)	Exercise Time (min:sec)	VO2 STPD (L/min)	VO2/kg STPD (ml/kg/min)	VCO2 STPD (L/min)	RER	VE BTPS (L/min)	O2 Pulse STPD (ml/beat)	Respiratory Rate (bpm)	Work (watts)	VE/ VO2	VE/ VCO2	Heart Rate (bpm)

□ Complete CPET CRF and initial, sign, and date the CRF where required.

□ Enter CRF data and upload exported excel file to REDCap via the following link:
https://redcap.research.cchmc.org/surveys/?s=CENNCKDJEX9HWKHM

Signatures:

_____	_____	_____
Exercise Physiologist Signature	Date (DD/MMM/YYYY)	Time

SAFETY CONCERN CHECKLIST

Site ID #:
_____
CKiD ID:
_____
Date of Test:
_____
Exercise physiologist:
_____
Clinician Reviewing the test:
_____

☐ No indications or safety alerts noted

Absolute indications for test termination (Select all that apply):

- ☐ ST-segment elevation (>1.0 mm) in leads without preexisting Q waves because of prior MI (other than aVR, aVL, and V1).
- ☐ Drop in systolic blood pressure >10 mm Hg, despite an increase in workload, when accompanied by any other evidence of ischemia.
- ☐ Moderate-to-severe angina.
- ☐ Central nervous system symptoms (e.g., ataxia, dizziness, near syncope).
- ☐ Sustained (defined as >30 consecutive seconds or unstable) ventricular tachycardia (VT) or other arrhythmia, including second- or third-degree atrioventricular (AV) block, that interferes with normal maintenance of cardiac output during exercise.
- ☐ Technical difficulties in monitoring the ECG or systolic blood pressure that may interfere with safety monitoring.

Relative indications for test termination include (Select all that apply):

- ☐ Marked ST displacement (horizontal or downsloping of >2 mm, measured 60 to 80 ms after the J point [the end of the QRS complex]) in a patient with suspected ischemia (in the absence of baseline ECG findings that interfere with repolarization such as a bundle branch block or LVH).
- ☐ Drop in systolic blood pressure >10 mm Hg (persistently below baseline) despite an increase in workload, in the absence of other evidence of ischemia.
- ☐ Increasing chest pain.
- ☐ Fatigue, shortness of breath, wheezing, leg cramps, or claudication.
- ☐ Arrhythmias other than sustained VT, including multifocal ectopy, ventricular triplets, supraventricular tachycardia, and bradyarrhythmias that have the potential to become more complex or to interfere with hemodynamic stability.
- ☐ Exaggerated hypertensive response (systolic blood pressure >250 mm Hg or diastolic blood pressure >115 mm Hg).
- ☐ Development of bundle-branch block that cannot immediately be distinguished from VT.
- ☐ If there is affirmative confirmation of high-quality pulse oximeter plethysmography tracing, hypoxemia with oxygen saturation of <85%.

Other safety concerns:

- ☐ Musculoskeletal injury
- ☐ Psychological or emotional event
- ☐ Other(s)

Describe all safety concerns related to this test indicated above:

Signatures:

_____	_____	_____
Signature	Date (DD/MMM/YYYY)	Time