The purpose of this supplement is to assist investigators and research personnel in drafting a research protocol and consent form for studies involving exercise testing.

Sections of this document include instructions to provide the user with a general overview of information required in the section. **The instructions and optional text are in blue** and required text is in black.

*Please note: This template is not the entire protocol or consent template. Please only use this template to inform your responses in the larger protocol and consent templates.*

**For the Protocol:**

1. Investigator Qualifications

**Additional Instructions for Studies Involving Exercise Testing**

A study team member must be trained in exercise testing administration. Exercise test supervision requires the ability to deliver a level of emergency care, as well as experience in exercise testing interpretation and emergency plan practice.

The study team’s qualifications should align with the risk level for the population being studied. Please see the sample ***VO2max and Submax Testing Risk Stratification*** form and the ***Skills Required to Competently Supervise Exercise Tests*** sample worksheet for recommended documentation of these skills.

1. Training and Oversight

**Additional Instructions for Studies Involving Exercise Testing**

The PI is responsible for ensuring the study team possesses the necessary skills related to exercise test supervision and the study population. The competencies for all study team members present during exercise should be documented.

1. Subject Population

* Inclusion and exclusion criteria: Provide a comprehensive list of criteria for enrollment.

**Additional Instructions for Studies Involving Exercise Testing**

Indicate the target population and risk level. Risk stratification should be completed utilizing the ACSM guidelines and/or the ***VO2max and Submax Testing Risk Stratification Worksheet***.

Please note: Women of childbearing age who are not medically sterile should be screened via urine pregnancy test and, if pregnant, should be excluded from VO2max testing.

1. Eligibility Screening

**Additional Instructions for Studies Involving Exercise Testing**

Screening must contain a health history including cardiovascular medical history, risk factors, symptoms, and other health issues. Please refer to the sample ***Health History Questionnaire***.

It is suggested that you utilize an eligibility screening form and submit it to the IRB for review. Please also refer to the ***VO2max and Submax Testing Risk Stratification Worksheet*** to determine risk level. Please provide rationale if deviating from these recommendations and provide substitute screening and risk evaluation procedures.

1. Risks

* **Risks of VO2max Testing:**
* Acute exercise may present a risk of untoward events, including sudden death
* Cardiovascular event (i.e., heart attack or cardiac arrhythmia)
  + Overall risk of cardiac events is about 6 events per 10,000 tests
* Serious injury
* Falling
* Physical discomfort
* Fatigue
* Muscle aches, cramps, joint pain
* Muscle strain and/or joint injury
* Delayed muscle soreness
* Abnormal blood pressure/heart rate
* Shortness of breath
* Lightheadedness, fainting
* Dizziness
* Nausea
* **Additional Instructions for Studies Involving Exercise Testing**

This section must include:

* + **Monitoring procedures**
    1. To include type of monitoring to be performed during test and by whom
  + **Individual stopping rules**
    1. If you choose to utilize different criteria than the ASCM stopping rules recommended below, please provide rationale for deviating from these recommendations and provide alternate stopping rules.
    2. *Provided as a guide, the ACSM recommends the following* ***stopping rules****:*
       1. *Subject requests to stop*
       2. *Onset of angina or angina-like symptoms*
       3. *Drop in SBP of >10mmHg*
       4. *Excessive rise in BP*
       5. *Shortness of breath, wheezing, leg cramps or claudication*
       6. *Signs of poor perfusion: light-headedness, confusion, ataxia, pallor, cyanosis, nausea or cold/clammy skin*
       7. *Failure of heart rate to increase with increased exercise intensity*
       8. *Noticeable change in heart rhythm*
       9. *Physical or verbal manifestations of severe fatigue*
       10. *Failure of the testing equipment*
  + **Emergency procedures** 
    1. Minimum requirements include:
       - AED located in same room as testing equipment
       - Routine testing of AED
       - Emergency action plan present at testing site
  + **Equipment handling and disinfection procedures**
    1. In addition, provide a copy of the manufacturers’ guidelines for applicable equipment

**For the Consent form:**

1. **What will happen if I take part in this research study?**

The study activities include VO2max testing. This is an exercise test that progresses from low to high intensity to measure the maximal rate at which your body can use oxygen during physical activity.

### WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

The possible risks and/or discomforts associated with the being in the study include:

**Risks of VO2max Testing:**

* + Acute exercise may present a risk of sudden death
  + Cardiovascular event (i.e., heart attack or cardiac arrhythmia)
* Overall risk of cardiac events is about 6 events per 10,000 tests
  + Serious injury
  + Falling
  + Physical discomfort from the test and equipment
  + Fatigue
  + Muscle aches, cramps, joint pain
  + Muscle strain and/or joint injury
  + Delayed muscle soreness
  + Abnormal blood pressure/heart rate
  + Shortness of breath
  + Lightheadedness, fainting
  + Dizziness
  + Nausea