

PROTOCOL TITLE: The Effect of Cardiovascular Fatigue on Performance of the  
Forward-Step-Down Test

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## 1.0 Objectives\*

- 1.1 The purpose of this study is to investigate the effects that a volitional maximal cardiovascular exertion test (the Bruce Treadmill Protocol) has on performance of the Forward-Step-Down (FSD) test, and to investigate how performance on the FSD test changes at multiple time points following the fatigue test.
- 1.2 Our hypotheses for this study are as follows:
  - Null ( $H_0$ ): Participants will not demonstrate a change in score on the FSD test after performance of the Bruce test at any time point.
  - Alternate ( $H_1$ ): Participants will demonstrate a change in score on the FSD test after performance of the Bruce test at one or multiple of the repeated measurements.

## 2.0 Background\*

- 2.1 The FSD test has been shown to correlate with movement quality. Deficits in strength and flexibility that result in movement impairments are associated with scores on the test delineating “moderate” movement quality.<sup>1</sup> Fatigue may play a role in increased injury risk, with fatigued participants in numerous studies showing compromised movement patterns that increase risk of injury.<sup>2-7</sup> At this time, many of the screening tools used to determine the impact of fatigue on a player’s ability to continue to play/practice involved dynamic or explosive movements,<sup>2,8-10</sup> and rely on indicators such as femoral internal rotation or hip adduction angles at initial contact to grade movement patterns. These biomechanical indicators may be difficult for non-professional personnel to observe, limiting their use outside a clinic. There is currently no research on the role of the FSD test in assessing for changes in movement pattern that result from fatigue.
- 2.2 N/A
- 2.3 The literature currently acknowledges that fatigue results in altered movement patterns. Several studies have investigated the impact that fatigue has on performing challenging movements, such as plyometric drop jumps,<sup>8</sup> cutting,<sup>2</sup> jumping and running,<sup>3</sup> and landing.<sup>7</sup> However, with higher level assessments such as these, there is an increased risk for injury if performed while fatigued.<sup>8</sup> Therefore, a lower level test, such as the FSD test, would be ideal as a safe and effective screening tool to look at the impact of fatigue stimulus (game play) on a person’s movement quality. As stated above, the FSD test has been validated as a measure of movement quality,<sup>1</sup> with acceptable interrater reliability.<sup>11</sup> In addition, poor movement quality during the FSD test has been shown to correlate with several impairments such as hip abductor strength and poor flexibility.<sup>1</sup> Existing literature discusses the impact of the hip abductors on knee position and risk for knee injury.<sup>2,3,5</sup> Therefore, a functional test that assesses not only movement quality but

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identifies possible causes of poor movement would be ideal for preventing injury. Research has shown difference in postural balance following aerobic fatigue depending on the time since fatigue,<sup>12</sup> with poor performance immediately following but improved performance 10 minutes after the fatigue stimulus was stopped. Therefore, this study will examine the FSD test at one, five, and ten minutes following the cardiovascular fatigue protocol in order to discern performance differences in movement quality related to time/recovery. These differences may be important because if the FSD test can be used as a screening tool to examine a person's fatigue level, it is important to also know the appropriate time to use the test in order to get accurate results.

In this study, the Bruce test is used to achieve cardiovascular fatigue. Clinically it is a "VO<sub>2max</sub>" (maximum volume of oxygen consumption) prediction test and is intended to continue to the point of failure (maximum test). In a true VO<sub>2max</sub> test, the participant performs the cardiovascular test until respiratory spirometry measures a plateau of the VO<sub>2</sub>, or oxygen consumption, between two workloads. This is indicative of that participant's maximum cardiovascular physiological limits. During a true VO<sub>2max</sub> test, respiratory gases are analyzed as well as heartrate, blood pressure, and sometimes blood lactate samples are obtained. Together these values determine the success in reaching a true VO<sub>2max</sub> test, demonstrate cardiovascular fatigue, and ensure safety of the participant. Often, this point is not reached in untrained or unhealthy individuals.<sup>13</sup>

Performing a true VO<sub>2max</sub> test is more expensive and time-consuming for the participant than performing a maximal or submaximal graded exercise test. Therefore, the Bruce protocol uses mathematical derivation to predict VO<sub>2max</sub> from the participant's performance on the Bruce. To estimate an accurate prediction of the VO<sub>2max</sub> and ensure cardiovascular fatigue, the target heart rate is often set at  $\pm 10$ bpm of the age-predicted maximum heart rate when using a lower error formula such as the Tanaka formula.<sup>14</sup> Therefore, in this study participants' age-predicted maximum heart rate will be calculated using the formula derived by Tanaka<sup>15</sup> with an acceptable variability of  $\pm 10$ bpm at the maximum heart rate measured during the Bruce. The Tanaka formula is accurate for a population of healthy men and women. In this study, "healthy" is defined as being in the "low risk" category for exercise as stated by the American College of Sports Medicine,<sup>16</sup> and is one of the inclusion criteria for this study.

### 3.0 Inclusion and Exclusion Criteria\*

- 3.1 Participants will be recruited from current physical therapy students in the class of 2020 who are enrolled in PHTH 7565. During the consent process, the participants will be screened using the American College of Sports Medicine's guidelines for safe participation in vigorous exercise.<sup>13,16</sup> By meeting the ACSM criteria, the participant is considered low risk for adverse events while participating in vigorous activity. Finally, in order for

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the student to participate, they must achieve  $\pm 10$ bpm of their predicted maximum heartrate, as calculated by the Tanaka<sup>15</sup> formula as stated above.

- 3.2 Exclusion criteria are pre-existing cardiovascular conditions or diseases that prevent participation in a maximal effort test without physician clearance per the ACSM guidelines.<sup>16</sup> Participants who do not reach their calculated target heart rate by the end of the Bruce protocol will be withdrawn from the study and will not complete post-fatigue testing.
- 3.3 The investigators plan to include the special population of students in this study. To mitigate potential risk of coercion, participation in the study will be voluntary. While the Bruce protocol testing is part of one of the mandatory laboratory activities for the exercise physiology class (PHTH 7565), participation in the study is not mandatory and it will be explained that participation in the study will not impact the students' grades in any class in any way. The testing will be performed as an adjunct to exercise testing performed in the regularly scheduled exercise physiology class, and the researchers are not responsible for grading in the exercise physiology class.

**4.0 Study-Wide Number of Subjects\***

N/A

**5.0 Study-Wide Recruitment Methods\***

N/A

**6.0 Multi-Site Research\***

N/A

**7.0 Study Timelines\***

7.1 Describe:

- Prior to performing the testing, participants will be consented and screened for inclusion and exclusion criteria at the end of an exercise physiology class during the summer 2018 semester. This will occur before the students begin their exercise testing labs in which the Bruce protocol is performed. Following consenting, participants will proceed to the testing during the four-week data collection period during the summer 2018 semester.
- Each participant will perform the pre-and post-testing in the same day. The pre-fatigue FSD test occurs just prior to the fatigue (Bruce) protocol, and the post-testing will occur at one, five, and ten minutes after completion of the fatigue protocol. Initial resting heart rate will be measured, as will heart rate at 0, 30, and 60 seconds following completion of the Bruce to ensure appropriate heart rate responses to exercise for a healthy young adult as per the inclusion criteria of

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participants being “low risk” for adverse events during vigorous exercise.

- The expected duration to obtain all necessary participants is up to 4 weeks.
- The estimated time for the researches to perform the primary analysis is 3 months
- The estimated time to prepare the manuscript for publication is 1 year.

## **8.0 Study Endpoints\***

- 8.1 The primary endpoint will be collection of the FSD test scores and maximum heartrate on the Bruce protocol. The secondary endpoint will be submission for publication.
- 8.2 During the fatigue (Bruce) protocol, the student will be monitored each minute for heartrate and rating of perceived exertion (RPE). Should either exceed safe values, or should the participant demonstrate adverse heart rate reaction to the exercise as stated in the ACSM termination criteria,<sup>13</sup> the test will be terminated. The participant also has control over the treadmill and can halt testing at any time should adverse events occur, or should the participant wish to stop the protocol. FSD testing will be halted if adverse events or injury occurs prior to or during the testing process. RPE has been established as a subjective correlation to physiological fatigue,<sup>17</sup> and is accepted as a non-invasive measure of physiological fatigue that will be used as a reinforcement of heartrate monitoring. There are no secondary safety end points.

## **9.0 Procedures Involved\***

- 9.1 This study will be a repeated-measures design, with all participants undergoing both pre- and post-fatigue FSD test assessments. Two orthopaedic specialist physical therapists will perform the FSD assessments. The investigators will review scoring guidelines per the Park article,<sup>1</sup> and will practice scoring the test prior to data collection to ensure good interrater reliability. Scores on the FSD test from each assessor will be averaged after data collection and prior to data analysis, with each assessor blinded to the other’s score prior to averaging the scores. Participants will be healthy physical therapy students. Fatigue will be induced via the Bruce protocol used in assessment of maximum cardiovascular capacity. The treadmill used is an HP Cosmos Quasar (HP Cosmos, Germany). The heart rate monitors used are Polar monitors (Polar Electro Inc, Bethpage, NY)
- 9.2 The FSD test grades the participant on movement quality during a repeated step down from a 20 cm step. The weight bearing leg will be the dominant leg (the leg the participant would use to kick a ball) as used in the Park et al<sup>1</sup> experiment. The FSD test consists of five repeated movements of the forward step down, with one score given for the whole set of five repetitions. For each set of five movements, the rater observes and produces

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one score for that set of five movements. For data analysis, the investigators will use the average of each score for each FSD test. For example, on the pre-test for a participant, if one investigator scored the pre-test FSD a 2/6, and the second investigator scored the pre-test a 1/6, the “averaged” score for the participant’s pre-test is a 1.5/6. This same procedure would be repeated for the three post-test FSD tests.

The Bruce protocol is self-limited with participants stopping at maximal exertion. Maximal exertion will be defined as  $\pm 10$ bpm of the participants predicted maximum heartrate as calculated by the formula “ $208 - (0.7 \times \text{age})$ ” derived by Tanaka from a population of healthy men and women.<sup>15</sup> The  $\pm 10$ bpm heart rate cutoff has been used as a benchmark of achieving maximal exertion in a maximal exercise test based off the calculated maximum heart rate using the Tanaka formula.<sup>14</sup> The participants’ Borg Rating of Perceived Exertion (RPE) will also be recorded as part of the Bruce protocol; however, since the participants know they will have to perform the FSD test following the Bruce protocol, the investigators will use heartrate instead of RPE as a metric for exertion due to its more objective nature and to avoid a possible threat to validity of the fatigue protocol. During the Bruce protocol, treadmill speed and incline are increased every three minutes until the subject volitionally stops the test at maximal exertion. Heartrate and RPE are monitored each minute during the Bruce protocol, with assessment of blood pressure prior and following the treadmill test as part of the Exercise Physiology class.

9.3 Table of events and tests to occur:

<b>Events/Procedure</b>	<b>Frequency</b>
Informed Consent	1
FSD test	4
Bruce test	1
Notification of results	1

9.4 Describe:

- Participants will be screened for health contraindications to performing the testing by use of the ACSM’s screen for participation in vigorous activity (see flow chart on Informed Consent document). No other data will be collected from the participant’s health record. They will be informed of their right to stop testing and withdraw from the study at any point. Heart rate will be monitored each minute during the maximal testing to ensure appropriate responses occur; testing will be

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halted by the investigators if heartrate fails to respond appropriately, the patient shows signs of hypoxia, or other injury/adverse events occur.

- N/A
- No source records will be required for the purposes of this study

9.5 The study will collect pre- and post-fatigue FSD test scores. Heartrate will be monitored and the maximum heart rate during the Bruce will be recorded to ensure the participant meets the  $\pm 10$ bpm cutoff, but will not be stored for further use.

9.6 N/A

## 10.0 Data and Specimen Banking\*

N/A

## 11.0 Data Management\* and Confidentiality

11.1 Since this study involves multiple repeated-measures over time, dealing with an ordinal level dependent variable, a Friedman's ANOVA would typically be used for data analysis. However, at least one previous study has analyzed this measure via parametric statistics, so we could potentially also pursue a Repeated Measures ANOVA if our data meets all parametric assumptions. Since our alternate hypothesis is two-tailed, our p-value will be divided by two for accurate significance assessment

11.2 To the investigators' knowledge, there is no previous literature examining the effects of an activity/intervention on a within-subjects change in performance on the FSD test. As a result, no within-subjects effects sizes were available for an a priori power-analysis for required sample size. In previous work examining the inter-rater reliability of the FSD test, Park, et al. used an effect size of 1.26, based upon the work of Rabin and Kozol, in which they measured the amount of ankle dorsiflexion and compared groups scoring differently on the FSD test in this anthropometric measure.<sup>17</sup> We therefore, used 0.5 as our effect size because the current study design differs from the Rabin and Kozol study design, and given their large effect size the investigators felt justified in setting a moderate effect size for the power analysis. The power analysis used an alpha of .05 and power of .80 for a two-tailed hypothesis via a repeated measures, within factors ANOVA analysis. This power analysis determined the need for nine participants. With 37 students in the class, we have more potential participants than needed to ensure the required power to observe a statistical result if it exists.

11.3 The Excel sheet will be kept in in a password protected file on password locked computers in the PI and co-investigator's offices. Consent forms will be secured in a locked file cabinet in the PI's office.

11.4 N/A

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11.5 Each investigator will track scores independently during the testing procedures, with a random number assigned to each participant recorded on the consent form and matched to the Excel data collection document. The results will be combined into a locked spreadsheet that will be stored on the PI's and co-investigator's laptops, which are both password protected. The only information collected that will be stored will be the patient's health screening and consent information which will be secured in a locked file cabinet in the PI's office, and the scores from the FSD test secured as stated. Following publication of the data, the informed consent documents will be retained for the requisite six years per HIPAA and LSUHSC-S IRB regulations. At this time, the records will be shredded. Both the PI and the co-investigator will have access to the data since the co-investigator will be responsible for statistical analysis of the data.

**12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects\***

The Bruce protocol is utilized in the many clinical exercise stress tests, and therefore is considered minimal risk because it is not greater than normal risk/discomfort expected during routine physical examination. In addition, the participants must all meet ACSM criteria that determine them to be low risk to participate in vigorous exercise. Therefore, the Bruce and FSD tests are not considered greater than normal activity for the participants of the study. However, the potential adverse events of exercise do include cardiovascular events such as myocardial infarction and death.<sup>18,19</sup> Therefore, these risks will be minimized as follows:

- Prior to consenting the participants, either investigator will give potential participants a health screen that will determine if they require a physician's clearance to undertake vigorous physical activity such as the Bruce protocol. Those who do need a referral will not be consented to participate until cleared by their physician if they still wish to participate. The screen is detailed by the American College of Sports Medicine (see Appendix A for the screening flow chart).<sup>16</sup>
- Participants will wear a heart rate monitor that will ensure the investigators are able to confirm appropriate cardiovascular response to exercise. Heart rate will be measured prior to and during testing each minute during the Bruce protocol. An adverse reaction to a maximal exertion test such as the Bruce protocol is a decrease in heart rate with the same or increased work load.

**13.0 Withdrawal of Subjects\***

13.1 Participants will be withdrawn without their permission if they demonstrate adverse reaction during the Bruce protocol that necessitates termination of the protocol prior to volitional maximum effort, as well as if they experience musculoskeletal injury during any portion of the test. Participants will be withdrawn if pre-testing blood pressure/heart rate monitoring reveals

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abnormalities that contraindicate Bruce Protocol testing. Participants will also be withdrawn if they do not meet the heart rate threshold during the Bruce protocol.

- 13.2 If the test must be terminated during the Bruce, the treadmill will be stopped and the participant monitored for normalization of hemodynamics, or appropriate medical procedures will be followed if necessary. Should participants be withdrawn before completion of the post-test FSD test, their data set will be removed from the analysis.
- 13.3 Data from participants who do not complete the final FSD test will be removed. Since testing is complete after the final FSD test, no further collection will need to be completed and participants do not need to return to the clinic.

#### 14.0 Risks to Subjects\*

- 14.1 Risks from performing the Bruce Protocol include muscle soreness and musculoskeletal injury, both of which are temporary and non-life threatening. Musculoskeletal discomfort is reversible with discomfort expected to pass within days. Since the participants are students who would be performing the Bruce Protocol tests for classroom experience, there is minimal economic or time burden.

More serious risks are possible, with a less than one percent risk for myocardial infarction and death due to over-exertion. Historically, this risk has been shown to be acceptable while performing cardiovascular stress tests with an estimate of 3.58 infarcts per 10000 tests and 4.78 serious arrhythmias per 10000 tests. The risk of death was 0.5 per 10000 tests.<sup>8 19</sup> However, cardiovascular stress tests are not performed in young, healthy populations because they are not deemed medically necessary for sports or activity participation. Therefore, these numbers represent adverse events that occur in the population that is recommended by a physician to undergo the cardiovascular stress tests. In this study, if a participant falls into a category that requires physician clearance before participating in exercise, they do not meet the inclusion criteria for this study.

In general the risk of death from sudden cardiovascular infarct during vigorous exercise remains low. The ACSM estimates one death per 1.5 million vigorous exercise training sessions in men, and one per 36.5 million hours of moderate-to-vigorous exercise in women. These numbers were drawn from participation in community gyms, where screening for exercise-risk does not always occur; therefore, the risk for these serious side effects is predicted to be lower due to the pre-test screening performed. Again, the risk noted above in the general population is most likely higher due to the careful medical screening that will occur as part of the inclusion criteria.

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14.2 There is no data regarding risks other than possible musculoskeletal discomfort from performing the FSD test. It is possible that injury may result from performing this test in a fatigued state but this is an unlikely risk.

14.3 N/A

14.4 N/A

**15.0 Potential Benefits to Subjects\***

15.1 Participants will be able to calculate their predicted  $VO_{2max}$  from the Bruce protocol data, which is useful for training purposes should the participants be aerobic athletes. Participants will also gain knowledge of their movement quality during the FSD test, which can be used to improve their deficits and potentially decrease injury risk. After data collection is complete, participants can contact the investigators to obtain their FSD test scores.

15.2 N/A

**16.0 Vulnerable Populations\***

The study does involve students of the university at which the investigators are instructors. The risk of coercion has been minimized by ensuring the participants give voluntary informed consent. In addition, the students participate in the Bruce protocol testing for one of their classes. Care was taken to select investigators who are not involved with grading of that class to ensure students do not perceive they are being coerced into participation in the study.

**17.0 Community-Based Participatory Research\***

Not applicable at this time; the goal of the investigators is to ultimately determine if the FSD test can be used as a screening tool for injury risk based on current fatigue levels. Should the study progress to that level, involvement with members of the community, such as coaches, will be included to determine if this is a feasible screening tool.

**18.0 Sharing of Results with Subjects\***

18.1 Should cardiovascular abnormalities be discovered in the heartrate and blood pressure screenings prior, during, or after the testing, the participant will be informed of the importance of following up with the appropriate medical professional. If desired, the investigators will provide the participant with a letter detailing the findings.

**19.0 Setting**

19.1 Describe the sites or locations where your research team will conduct the research.

- Participants will be identified by the cohort who will be enrolled in Exercise Physiology (PHTH 7565) in the summer of 2018.

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- Research will be conducted at the School of Allied Health Professions Faculty Practice Clinic.
- N/A
  - N/A

## 20.0 Resources Available

20.1 Both investigators have completed orthopaedic residencies and hold current licenses to practice physical therapy in the state of Louisiana. The co-investigator is an Orthopaedic Clinical Specialist, and the PI has recently taken the Orthopaedic Clinical Specialist exam and is awaiting results. PT licensure includes indications and contraindications for maximal exercise testing and prescription for various healthy and unhealthy populations. In addition, the PI has experience working with exercise testing at the Pennington Biomedical Research Center in Baton Rouge, LA. The co-investigator is currently completing his PhD work in Physical Therapy.

20.2 Describe other resources available to conduct the research: For example, as appropriate:

- The class of 2020 that will be enrolled in Exercise Physiology has a total of 37 students. With nine participants needed per the power analysis, there should be no difficulty recruiting the necessary number of participants.
- Both investigators are instructors in the School of Allied Health Professions in the Department of Physical Therapy, and have 30% of their time set aside for research purposes. This time will include recruitment and consenting of participants, testing, data analysis, and writing results for publication.
- The Faculty Practice Clinic in the School of Allied Health Professions is a functioning outpatient physical and occupational therapy clinic. It includes treadmills for aerobic testing, and the appropriate equipment to perform the FSD test. It also includes the emergency equipment necessary to be a functional clinic within regulation.
- The School of Allied Health Professions is part of the larger Health Sciences Center campus. Emergency transportation is available to the hospital, which is adjacent to the Medical School portion of campus. In addition, students have mental health services available for free through the School should this be necessary if a participant has an adverse psychological event to the testing procedures.
- All participants will give voluntary informed consent, by which they will be educated on what tests they will be expected to perform. Both investigators will be able to consent participants into the study. Both investigators will review the protocol prior to the testing sessions, and will keep independent records of FSD test. Prior to each testing sessions, the investigators will clarify any questions regarding

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procedure to ensure the same progression of tests are performed on each participant.

### **21.0 Prior Approvals**

21.1 Permission will be obtained from the Exercise Physiology Course Coordinator to add the FSD test pre- and post-testing to the Bruce protocol laboratory experience.

### **22.0 Recruitment Methods**

22.1 Participants will be recruited from the physical therapy students enrolled in PHTH 7565 Exercise Physiology at the School of Allied Health Professions in the summer of 2018.

22.2 The participants will be from the DPT Class of 2020.

22.3 All students in the above class who do not meet the exemption criteria will be eligible.

22.4 N/A: an announcement will be delivered to the Exercise Physiology class regarding the experiment and consenting process.

22.5 N/A

### **23.0 Local Number of Subjects**

23.1 One hundred percent of the subjects will be recruited locally. As stated in the inclusion/exclusion criteria, participants will be included for post-testing only if they achieve  $\pm 10$ bpm of their predicted maximum heartrate on the Bruce protocol. Participants will be informed of the study, screened, and consented to participate at one time. During testing, participants will be gathered until adequate power is reached.

23.2 The physical therapy class the participants will be drawn from has 37 students total. All willing participants will be screened and consented for inclusion, and data will be gathered until adequate power is reached.

### **24.0 Provisions to Protect the Privacy Interests of Subjects**

24.1 Due to the nature of the Bruce Protocol testing for the Exercise Physiology class, students will be visible to their classmates during testing. However, participants will have the ability to request screens be placed around the area where the FSD test occurs to ensure privacy.

24.2 Participants will be educated on the nature of the tests that they will be performing, as well as the risks and benefits associated with research participation. They will be allowed three minutes of familiarization prior to the pre-testing portion of the FSD test.

24.3 The investigators will inquire about past medical history in order to ensure the participant meets the inclusion criteria. Access to medical records is not otherwise required.

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**25.0 Compensation for Research-Related Injury**

25.1 N/A

25.2 N/A

**26.0 Economic Burden to Subjects**

N/A

**27.0 Consent Process**

27.1 Indicate whether you will be obtaining consent, and if so describe:

- Consent will take place in the classroom with all students present. Those wanting to participate will be screened with the ACSM medical screen, and there will be time for questions regarding the testing both as a group during the information and consent session, and individually by appointment with the PI or co-investigator within the one week following the informational session.
- Participants will be informed that they have up to one week to consent for the study after the general information is given. They will be given the contact information for both investigators, and both investigators will be able to consent a participant in the study.
- Participants will be reminded that they are able to withdraw at any time.
- The study will be following “SOP: Informed Consent Process for Research (HRP-090).”

***Non-English Speaking Subjects***

- N/A

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

- N/A

**Subjects who are not yet adults (infants, children, teenagers)**

- N/A

**Cognitively Impaired Adults**

- N/A

**Adults Unable to Consent**

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- N/A

**Adults Unable to Consent**

- N/A

**28.0 Process to Document Consent in Writing**

28.1 The study will follow “SOP: Written Documentation of Consent (HRP-091).”

28.2 Given the special population of students in this study, the investigators decided to obtain written informed consent.

28.3 Consent Document attached with ACSM medical screening to be performed at the time of informed consent.

**29.0 Drugs or Devices**

- N/A

- N/A



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