Appendix C.

Consent Form

I hereby give my consent for my participation in the research project entitled: the effects of caffeine consumption on core body temperature in the physical active during exercise. I understand that the people responsible for this research project are: Amy Menzies, ATC, LAT and Amanda Martinez ATC, LAT of the Department of Health and Human Performance, Telephone Number (512) 245-2561. Amy can be reached via email at am1911@txstate.edu and Amanda can be reached at am1913@txstate.edu.

I. Caffeine consumption is on the rise and has been shown to increase physiological effects on the body, mainly core body temperature. Caffeine consumption when applied to the physically active evokes a concern of the potential inability to maintain thermoregulation. Taking into consideration the possible physiological effects of caffeine, it is important to determine if a limitation of its use with the physically active population is needed. Participants will be given caffeine supplementation and a placebo to compare the difference in rise of core body temperature.

The study population will consist of at least 15 healthy males (18-30 years of age) subjects that are physically active yet not involved in competitive sports. In addition, individuals who currently smoke, are overtly obese, have a history of known cardiac, respiratory or metabolic disease or musculoskeletal disease that would limit exercise participation, are currently experiencing a major physical or mental illness, or are currently taking medication for a major physical or mental ailment will be excluded from participating. For this reason answer the questionnaire to the best of your ability. Some examples of the questions are: How much caffeine do you consume; as well as Have you ever experienced shortness of breath while walking/running?

Before I undergo any exercise testing, I certify to the program that I am in good health and to my knowledge am not currently pregnant. It is my understanding that I will be interviewed by trained professionals prior to my undergoing the test who will in the course of interviewing me determine if there are any reasons which would make it undesirable or unsafe for me to take the test. Consequently, I understand that it is important that I provide complete and accurate responses to the interviewer and recognize that my failure to do so could lead to possible unnecessary injury to myself during the test. You may refuse to answer the questions, but doing so may disqualify you from participation.

I hereby consent to voluntarily engage in an exercise test to determine my physical fitness. I also consent to the taking of samples of my exhaled air during exercise to properly measure my oxygen consumption. I also consent to the performance of an endurance exercise ride for 40 minutes on a bicycle at 55% -60% of the exercise intensity I completed on the maximal test, in a hot (370C, 33%RH). I also consent to consume randomly 6mg/kg of body weight of caffeine and/or a placebo. For example a person weighing 180 lbs weighs 81 kg. After doing the math they would consume 486 mg of caffeine. This is approximately equal to consuming two 8 oz cups of generic brewed coffee and an 8 oz Rockstar energy drink. I also consent to swallow a core temperature pill prior to the beginning of each of the endurance exercise rides.

The exercise testing I will undergo will be performed on a bicycle. As I understand it, my personal understanding of effort will continue until I feel and verbally report to the operator any symptoms such as fatigue, shortness of breath, or chest discomfort which may appear. It is my understanding and I have been clearly advised that it is my right and obligation to request that a test be stopped at any point if I feel unusual discomfort or fatigue. I have been advised that I should immediately upon experiencing any such symptoms, or if I so choose, inform the operator that I wish to stop the test at that or any other point. My wishes in this regard shall be absolutely carried out. I have also been advised that I may withdraw from participation in this study at any time. **I also understand that full participation for the length of this protocol will last approximately 3 weeks.**

A summary of findings will be provided to participants upon completion of the study if requested.

**II. Risks**

I understand and have been informed that there exists the possibility of adverse changes during the actual test. I have been informed that these changes could include abnormal blood pressure, fainting, disorders of heart rhythm, stroke, and very rare instances of heart attack or even death. I may also experience muscle soreness following the test. I have been told that every effort will be made to minimize these occurrences by precautions and observations taken during the test. I have also been informed that trained CPR personnel will be available on site during all exercise bouts. I understand that there is a risk of injury, heart attack, or even death as a result of my performance of this test, but knowing those risks, it is my desire to proceed to take the test as this form describes it. Additional risks of caffeine consumption include but are not limited to the following: restlessness, irritability, anxiety, heartburn, headaches (sometimes severe), high blood pressure, sleeplessness, rapid heartbeat, nausea. Potential risk of an increase in core body temperature to the upper safe limit of approximately 100°F (39° C) could result in a hyperthermic state. Furthermore, I understand that if this research project causes me any physical injury, treatment is not necessarily available at Texas State University or the Student Health Center, nor is there necessarily any insurance carried by the University or its personnel applicable to cover any such injury. Financial compensation for any such injury must be provided through my own insurance program. Further information about these matters may be obtained from Institutional Review Board Chair: Dr. Jon Lasser: Phone Number: 512-245-3413 or Compliance Specialist: Ms. Becky Northcut: Phone Number: 512-245-2102.

Both researchers Amy Menzies and Amanda Martinez are nationally certified athletic trainers, state licensed athletic trainers, CPR/AED and First Aide certified. They have both been trained to identify emergency situations and how to properly offer emergency treatment if such occurrences should arise. Both researchers will be present during each experimental trial.

# **III. Benefits to be expected**

The results of this test may or may not benefit me. Potential benefits relate mainly to my personal motives for taking the test, that is, knowing my exercise capacity in relation to the general population, understanding my fitness for certain sports and recreational activities, planning my physical conditioning program, or evaluating the effects of my recent physical activity habits. Benefits of caffeine consumption include but are not limited to the following: increase mental awareness, increase muscle strength, reduce asthma symptoms, increase pain relief medication affects, and increase metabolism.

# **IV. Confidentiality and use of information**

I have been informed that all information obtained from these testing procedures will be treated as privileged and confidential and will consequently not be released or revealed to any person without my express written consent. I do, however, agree to the use of any data recorded for research or statistical purposes so long as it does not provide facts that could lead to my identification. Any other information obtained, however, will be used only by the program staff to evaluate my exercise status or needs.

# **VI. Inquiries and freedom of consent**

# I fully understand that my participation in this research project is voluntary and that refusal to participate involves no penalty or loss of benefits to which I may be entitled, and that I may discontinue participation at any time without penalty or loss of benefits.

I further understand that there are also other remote risks that may be associated with this procedure. Despite the fact that a complete accounting of all these remote risks has not been provided to me, I still desire to proceed with the test.

I acknowledge that I have read this document in its entirety or that it has been read to me if I have been unable to read same.

I consent to the rendition of all services and procedures as explained herein by all program personnel.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_

Participant’s signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_

Project Supervisor’s Signature