**Sample Adult Consent Form for Non-Therapeutic Research Greater than Minimal Risk**

**Adult Informed Consent Form**

**IRB #030317-1**

**Title of Research Study:**  The Effects of Exercise Duration on Salivary Levels of Immunoglobulin A (IgA)

**Summary**

The purpose of this study is to examine the effect of exercise duration on the concentration of a substance in your saliva that helps fight infection. You might decide to participate in this study because you will learn about your aerobic fitness level and how exercise affects the level of this substance in your saliva. You might decide not to participate in this study because of the risks associated with the treadmill tests. The maximal treadmill test will cause you to experience some breathing discomfort and/or muscle soreness because it is a very intensive running activity. You’ll have to use a mouthpiece during these tests, which could be uncomfortable and cause soreness. Injuries from an accidental fall during the test are possible, and you might experience muscle and joint soreness following the test. There is a possible risk of sudden death, but this is unlikely based on your age and fitness level as determined by the Health History Questionnaire you will take to qualify for the study. You’ll also have to report to the Human Performance Lab four times over a two-week period for periods of time ranging from 15-60 minutes.

**Invitation to Participate**

You are invited to participate in this research study.  The following information is provided in order to help you make an informed decision whether or not to participate.  If you have any questions, please do not hesitate to ask.

**Basis for Subject Selection**

You are eligible to participate because you are a healthy male between the ages of 19 and 29, who exercises less than three times per week.

**Purpose of the Study**

The purpose of this study is to determine the effects of exercise duration (the length of time a person exercises) on salivary Immunoglobulin A (IgA) concentration.  IgA is a substance that is found in the saliva that plays a role in preventing infection by viruses.

**Explanation of Procedures**

This study will take two weeks to complete during which you will be scheduled for four different exercise sessions in the University of Nebraska at Kearney Human Performance Lab.  The following are the procedures you will undergo if you agree to participate in this study:

**Health History Questionnaire:**

You will complete a Health History Questionnaire during your first visit to the Human Performance Lab.  The questionnaire, which will take about 15 minutes, will provide your health history including diagnoses of illness and/or medical problems, history of surgeries, use of over-the-counter and/or prescription drugs, allergies, personal health and exercise habits, and your family health history.  Individuals who are potentially at risk associated with the exercise required in this research should not participate in this study, or they will be required to obtain a physician’s clearance before participating.

**Maximal Treadmill Test:**

During your initial visit to the Human Performance Lab, the maximal treadmill test will be conducted in order to determine your maximal ability to perform aerobic exercise.  This is based on the maximum capacity of an individual's body to transport and use oxygen during incremental exercise (VO2max).  Before the text begins you will be asked to sit quietly. Following several minutes of rest, your blood pressure will be measured, and a mouthpiece will be placed in your mouth in order to measure ventilation and the oxygen and carbon dioxide concentration of the inhaled and exhaled air. VO2max is reached when oxygen consumption remains at a steady state despite the increase in workload. Your heart rate responses will be monitored by electrodes taped to your chest.

You will then begin walking on a motor driven treadmill.  At the start of the test the treadmill speed will be a slow (4 mph), and you will walk on a level surface.  Every three minutes the speed will be increased 1 mph up to 9 mph.  When you reach a speed of 9 mph, no further increase in speed will occur.  Instead, the treadmill surface will be raised 2 degrees every three minutes until you can no longer continue.  You will be encouraged to give your best effort at the end of the test. The test will take about 60 minutes.

The test will be completed when you indicate that you do not wish to continue on to more demanding exercise.  If you do not give such an indication, the test will be completed when your responses (heart function, breathing rate, and/or physical appearance) indicate that either you should not continue or that you have reached your peak effort.  Following completion of this test, the speed and incline of the treadmill will be decreased so that you may recover at a slow jogging pace on a level surface for as long as you like.

**Submaximal Treadmill Test:**

One week after the maximal treadmill test and for two subsequent sessions at the Human Performance Lab, you will return to the Human Performance Lab to complete a series of three submaximal treadmill tests. You will perform these tests at an intensity that is equal to 60 percent of your previously determined VO2max.  Each of the tests will require about 60 minutes.  The tests will be performed at least 48 hours apart and as close to the same time of day as possible.

To start the submaximal treadmill test, you will be allowed a 5-10 minute warm-up at a walking speed (4 mph).  The speed will then be increased so that you will be running at 60 percent of your VO2max for 50 minutes.

**Salivary Analysis:**

Saliva samples will be taken at the time of each of the exercise sessions.  The saliva sample will require that you expectorate (spit) into a test tube.  Two saliva samples will be taken at the time of the maximal treadmill test, one before the test and one following the test.  Two saliva samples will be taken at the time of each of the submaximal tests.  These samples will be taken before the start of each run and five minutes after each run.

**Potential Risks and Discomforts**

The following are the risks and discomforts you could potentially experience during this study:

**Maximal Treadmill Test:**

As a result of the maximal treadmill test you may experience, for a short time, some breathing discomfort and/or muscle soreness similar to what you may have experienced during or following intense running and/or exercise.  The mouthpiece may be uncomfortable during the test and may cause some soreness in the mouth.  You should be aware that these tests involve the possible risk of falls and/or muscle-joint injuries.  Some muscle soreness may also be experienced following the test.  Sudden death is also a possible risk.  However, considering your age and fitness level as determined by the Health History Questionnaire, sudden death is unlikely.

**Submaximal Test:**

The submaximal treadmill tests should not cause any undue discomfort, except for some muscle fatigue toward the end of the test. Other risks such as muscle-joint injuries and sudden death are also possible risks, but are considered highly unlikely.

**Salivary Analysis:**

No known risks are associated with the salivary analysis.

**Protection Against Risks**

A person certified in CPR will be present throughout all exercise procedures.  Subjects also will be shown appropriate stretching maneuvers in order to alleviate muscle soreness.

**Potential Benefits to Subject**

You will receive feedback about your aerobic fitness level. It also may be of interest to you to see what changes, if any, in salivary IgA levels occur following a bout of exercise of a particular duration and intensity.

**Potential Benefits to Society**

Results from this study may help to determine if exercise of a certain duration and intensity affect susceptibility to upper respiratory infections.

**Alternatives to Participation**

The alternative to participation is not to participate.

**Assurance of Confidentiality**

Your participation in this study is voluntary.  Any information obtained in this study that could identify you will be kept strictly confidential.  Your name will not be associated in any way with the research findings.  The information obtained in this study may be published in scientific journals and presented at professional meetings, but only as aggregated date.  Your information will be identified only by a code number, and will be stored in a secure filing cabinet and computer database in the Human Performance Laboratory at UNK.

**Compensation for Participation**

There is no financial compensation for participating in this study.

**In Case of Emergency Contact Procedure**

In the event of a research-related injury, or if you experience an adverse reaction, please immediately contact one of the investigators listed at the end of this consent form.

**Emergency Care and Compensation in Case of Injury**

In the unlikely event that you should suffer an injury as a direct consequence of the research procedures described above, no additional compensation for physical care, hospitalization, loss of income, pain, suffering, or any other form of compensation will be provided.  None of the above shall be construed as a waiver of any legal rights or redress you may have.

**Rights of Research Subjects**

Your rights as a research subject have been explained to you.  If you have any additional questions concerning your rights as a research subject, you may contact the Institutional Review Board (IRB) of the University of Nebraska at Kearney, phone (308) 865-8496.

**Voluntary Participation and Withdrawal**

You are free to decide not to participate in this study or to withdraw at any time without adversely affecting your relationship with the investigators, or the University of Nebraska at Kearney.  Your decision will not result in any loss of benefits to which you are otherwise entitled.

**Documentation of Informed Consent**

You are voluntarily making a decision whether or not to participate in this research study.  Your signature certifies that the content and meaning of the information on this consent form have been fully explained to you, and that you have decided to participate having read and understood the information presented.  Your signature also certifies that you have had all your questions answered to your satisfaction.  If you think of any questions during this study please contact the investigators.  You will be given a copy of this consent form to keep.

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Printed Name of Subject                                                    Date

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Signature of Subject                                                          Date

My signature as a witness certifies that the subject signed this consent form in my presences as his/her voluntary act and deed.

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Printed Name of Witness                                                   Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Witness                                                          Date

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

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Signature of Investigator                                                    Date

**Identification of Investigators**

                    **Principal Investigator**

                    Bill Wild, Ph.D.            University of Nebraska at Kearney

                    Office : 865-1111        Home: 236-3337

                    **Secondary Investigator**

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