Procedures/Risks: exercise/energy testing_template

Energy Measurement (indirect calorimetry)

Procedure: During the study, you will have your resting energy (calorie) needs determined by indirect calorimetry using an instrument called the Deltatrac™ Metabolic Cart. This method calculates your body's use of calories by comparing the amount of oxygen you breathe in to the amount of carbon dioxide you breathe out. The airflow of oxygen and carbon dioxide will be measured while you are lying down in a hospital bed with a clear, plastic, ventilated canopy over your head and a plastic apron over your upper body. The test will take approximately 20 minutes. During this time, you should be relaxed, lie still, and breathe normally. If at any time during the measurement you should feel that you need to remove the canopy, you can easily lift it off your head.

Risks: You may experience claustrophobia (a fear of enclosed spaces) during the measurements that use the DeltaTrac Metabolic Cart. There is no physical danger involved with these measurements. The DeltaTrac has a well-ventilated canopy that will cover your head and neck. At any time, you may easily remove the canopy by lifting it over your head. These are important measurements for the study, and if you do not feel safe participating in the DeltaTrac measurements, you will not be enrolled or continue to participate in the study.

Exercise Testing or VO_{2max} test (or sub-max test):

Procedure: Exercise testing is designed to measure your level of physical fitness. The exercise stress test will measure how well your heart responds to exercise. You will wear your exercise clothing (t-shirt and tennis shoes) for the test. The nurse [technician/exercise physiologist] will place plastic pads or electrodes on your chest wall to measure your heart rate and rhythm. Your blood pressure will also be measured at this time. The nurse [technician/exercise physiologist] will instruct you to wear a mouthpiece. This will help measure the amount of air you breathe in and out. The amount of oxygen you breathe also will be measured. You will be asked to exercise up to a certain level of effort [until you are exhaused]. During the test, your heart rate, blood pressue and oxygen level will be monorited and you will be asked to rate your percieved level of exertion by pointing to a standardize chart. If you feel faint or uncomfortable, then you can request that the exercise test stop.

Procedure: A VO2max test will be used to measure the amount of oxygen that is used during exercise. You will pedal on a stationary bicycle while breathing into a soft rubbery mouthpiece. Electrodes will be placed on your body to monitor your heart activity throughout the session. A blood pressure cuff will be placed on your arm to monitor your blood pressure for each minute that you are cycling. Once you begin cycling, the difficulty will increase until you can no longer

continue. During this visit, a small needle (catheter) will be placed in your arm so that your blood can be drawn [at X different times].

Risk: The risks associated with the exercise stress test are fatigue, muscle soreness, irregular heart beat, chest pain and sudden heart attack. To minimize these risks you will have a trained exercise physiologist performing this procedure. In addition, you will have your heart rate monitored continuously throughout the test. You will have your blood pressure and your rate of perceived exertion monitored throughout the test. The test will be discontinued if any abnormal heart rate or rhythm, blood pressure is detected.

Risk of an exercise program includes shortness of breath, cramping, and abnormal blood pressure. In rare cases there is a risk of abnormal heartbeat, heart attacks, stroke, or even death. *You will have to get a letter from your regular physician before you start this exercise program stating that it is alright for you to take part in the exercise program***.**

The risks associated with an exercise treadmill test are about the same as those that may happen during strenuous athletic events. The risks include occasional irregular heartbeat or abnormal blood pressure. There is a small chance of a heart attack. Severe irregular heartbeat, heart attacks, stroke, or death are extremely rare in adults with a normal health history.

Risks: The exercise [VO2max] testing may cause some physical discomfort. Upon its completion, you may experience temporary muscle aches and joint pain. Although extremely rare, there is a minimal risk of serious injury or death. This test will be monitored by a physician if it is determined that you are at moderate or high risk to complete this procedure.

For language on submaximal exercise testing, visit:
http://gcrc/core_info/bionutrition/bionutrition_investigator.php

VO_{2max} test

Procedure: For this study, you will be asked to participate in a maximal [graded] exercise test to evaluate your aerobic fitness. This test will require you to walk or jog on the treadmill until you are physically exhausted. It will begin with a paced walk and will gradually increase in speed and/or incline every three minutes. The test is over when you feel you cannot continue or if the researcher determines the test should end due to one of the following: the researcher feels you have reached your maximal exercise capacity; the researcher does not feel it safe to continue, or equipment malfunction.

A typical test will last between 8-12 minutes depending on your fitness level. During the test you will breathe into a mouth piece, which looks like a snorkel. Your nose will be gently pinched shut by a soft plastic clip, so that you may only breathe through your mouth. The air you inhale will be normal room air. The air you exhale will go into the mouthpiece and through a tube. The tube is connected to a device that analyzes the volume and concentration of oxygen and carbon dioxide you exhale. Your blood pressure will be taken automatically in every third minute of the test. A continuous 12-lead ECG will be monitored to ensure your safety during exercise. You will be encouraged to continue the test as long as

possible. However, you are free to stop the test at any point if you wish, even if you are not at maximal fatigue.

Risk: There is a possibility of certain changes occurring during the test. These include, but are not limited to, abnormal blood pressure, chest pain, shortness of breath, fainting, disorders of the heart beat (too rapid, too slow or unusual beats) and in rare instances, heart attack. Every effort will be made to avoid or minimize such occurrences by the physician's clearance and by observations during testing. Emergency equipment and trained personnel are available to deal with unusual situations which may arise.

Lifecorder®

Procedure: You will be asked to wear a Lifecorder® on your belt for …during the study. The Lifecorder® is a lightweight device about the size of a pager that records physical activity.

Risks: Beyond possible discomfort or inconvenience, there are no known risks in using the Lifecorder®.

One mile walk:

Procedure: [At the first visit] You will be asked to do a 1-mile walk. The walk will also help the researchers decide if you should take part in the study. It is very important that during the walk you tell the researchers if you have any problems or need to stop the walk. If you are able to complete the 1-mile walk in the time required by the study, and without any physical problems, then the researchers may ask you to continue with the study. If the researchers feel that you are not able to take part in the study, then they will let you know. You should also tell the researchers *if you feel like you are not able to take part in the study*. If you continue you will be asked to return for the remainder of the study visits and procedures as are described in this consent document.

Six minute walk test:

Procedure: This test measures the distance you can walk on a flat surface in six minutes at a pace that you can maintain. You are allowed to stop and rest during the test if you need to do so.

Procedure: The six-minute walk test will involve walking as far as you can for six minutes. This will be done on level ground and you will be given oxygen if you need it. Your oxygen will be measured by a wrap-around sensor worn on your finger. If you become too tired or short of breath during the test, you can sit down and rest for as long as you want.

Risk: You may experience leg cramps, shortness of breath, chest pain or fatigue. You may require oxygen during your walk. You will be monitored continuously for oxygen level and heart rate during the walk.