

Food Frequency Questionnaires, Body Composition Measures and Mixed Meal studies

Procedures/Risks_template

For further template language related to diet analysis, body composition, metabolism and exercise physiology, including, but not limited to, grant methodology, manuscript methodology, validity and consent, visit:

http://gcrc/core/info/bionutrition/bionutrition_investigator.php

Basic Body Measurements

You will have standard measures of height, weight, respiratory rate and heart rate taken.

The nutritional assessment will include measurements of your height, weight, and body fat. A nutritionist will interview you regarding the foods that you eat as part of a nutritional assessment.

Energy Measurements

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 which has been placed over your head for the test, then 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.

Food Frequency Questionnaires

Procedure: In order to assess your nutritional intake, you will complete a Food Frequency Questionnaire (FFQ) that asks questions about the kinds of food that you eat. You may be asked

to complete this questionnaire either on a computer, an electronic tablet, by pencil and paper, or through an interview with a trained member of the research team.

Risk: There are no known risks to completing the Food Frequency Questionnaire(s).

Benefits: You will receive a report from the Food Frequency Questionnaire that will provide useful personal information about the kinds of nutrients in your diet, as well as intake of key food groups, especially fruits, vegetables, and grains.

You will receive reports based on your answers on the Food Frequency Questionnaire. These reports will tell you about your eating patterns, for example how closely the number of servings in each food group that you eat each day matches the United States Department of Agriculture's (USDA) recommendations. In addition, this report will show your average daily intake of different nutrients and recommendations for improving your diet.

Body Composition

Bioelectrical impedance analyzer (BIA):

Procedure: Bioelectrical impedance analyzer (BIA) is a technique used to determine fat free mass (FFM) and lean body mass {muscle} (LBM) and body fat mass (BFM). BIA is a device that uses a safe low level electrical current through body fluids in fat tissue to measure body composition such as fat mass. During this procedure you will lie flat on a bed with minimal clothing. Plastic pads or electrodes will be placed on your right hand and foot. Your body composition is measured by the machine.

The amount of body muscle and fat that make up your body will be determined with a small portable device that measures how your body reacts to a flow of very weak electrical current. After you lie down on a bed [in the CRC], you will have 2 'sticky tab' electrodes attached to your right foot and hand, which will then be connected to the BIA with alligator clips. Because muscle is a good conductor, the very small current generated by this device will readily pass through it, whereas fat tissue will hinder the current's passage. This test will take approximately 2 minutes, during which time you will lay quiet and still on the bed.

Prior to having this test conducted you must not have consumed any food or beverages (except water) within the past 8-12 hours, any caffeine (e.g. coffee, tea, soda-pop, energy drinks) or alert-enhancing pills (i.e. Vivarin, No-Do's, etc.) within 4 hours or have exercised within 4 hours. These things can distort the accuracy of the measurement(s).

Risk: There are no known risks to BIA. The bioelectric impedance analysis (BIA) uses a very small electrical current, which passes between electrodes placed on the hand and foot. The amount of this current is slight enough that it cannot be felt and poses no risk to humans. However, there is a slight risk that this low current could disrupt an artificial pacemaker or defibrillator.

The bioelectrical impedance analyzer (BIA) has a minimal electrical current similar to

that of electrocardiogram (EKG), a machine that is routinely used to measure heart beat and heart rhythm.

If you have an artificial pacemaker or defibrillator, then [for your own safety] you will not be allowed to participate in the study.

From having not eaten any food you might experience a drop in blood sugar and feel lightheaded and nauseous. If these should occur, please notify one of the researchers, nurses or technicians, in order that they may help you. [At the completion of this testing, a small snack (or meal) will be provided to you.]

Body Composition Procedure Using the Bod Pod:

Procedure: Estimates of body composition (fat versus fat free mass) will be completed by applying measures of body volume and body density obtained from air displacement plethysmography (ADP) in the Bod Pod (Life Measurement, Inc. Concord, CA). Standard ADP procedures include obtaining subject height, weight, thoracic (body trunk) gas volume, and air displacement. The latter two are measured inside the Bod Pod chamber. Prior to testing the subject is weighed. **Subjects are required to wear a swimming cap and bathing suit (or spandex outfit) during the test**, which lasts approximately 5-10 minutes.

You will have your body muscle and fat measured while wearing a bathing suit and cap when sitting in a device called the BodPod. The Bod Pod resembles an egg-shaped chamber, and has a window for you to look out and air will move in the enclosed space where you sit. While enclosed in this chamber, if you begin to feel uncomfortable, you can press a button located by your knee to open the door. The Bod Pod measures the air flow and the changes in the air flow that occur while your body is in the chamber. You are to sit quietly while the first measurements of air flow are conducted. The technician will then instruct you on breathing properly through a tube, using only your mouth while your nose is clamped, in order to measure the volume of air in your lungs. The final procedure in measuring the amount of air in your lungs will require that you puff three times into the tube; as if laughing. The whole test takes approximately 15 minutes, but may be longer if you have any trouble performing the proper breathing techniques which may need to be repeated.

Risks: During the Bod Pod testing it is possible that you might experience some lightheadedness or dizziness. It is also possible that if you are claustrophobic, that you may begin to have a feeling of being shut-in. A button at your knee while you are inside of the Bod Pod, will allow you to have the door of the Bod Pod open *immediately*. A window on the Bod Pod also will allow you and the technician to see and communicate with one another.

You may experience claustrophobia (a fear of enclosed spaces) during the measurements that use the Bod Pod [and the DeltaTrac Metabolic Cart]. There is no physical danger involved with these measurements. Room air is continuously circulated through the Bod Pod compartment when it is closed. The compartment does not lock and the person inside can exit at any time. [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 BodPod [or DeltaTrac measurements], you will not be enrolled or continue to participate in the study.

DEXA:

Procedure: Dual-energy x-ray absorptiometry (DXA or DEXA) is a standard procedure to measure body composition. It measures whole body fat, lean body mass (muscle) and bone density as well as regional body fat. After a technician has explained the procedure to you, you will lie flat on the DEXA table. X-rays from the machine will be introduced into your body. The absorption of the x-rays of your body tissue will be determined by the computer in the machine.

Risk: The radiation emitted from the DEXA is less than that of a chest x-ray.

The radiation exposure from the bone density machine (DEXA) is usually compared to the amount of exposure from one chest x-ray. Therefore, risks associated with DEXA is similar to exposure from a chest x-ray. Similarly, the bioelectrical impedance analyzer (BIA) is associated with minimal electrical current similar to that of electrocardiogram (EKG), a machine that is routinely used to measure heart beat and heart rhythm.

The amount of radiation you will be exposed to from the DEXA scan is extremely small. This is a standard test that is performed in the study exactly the same as it is for regular patient care. The exposures for the DEXA are as follows: about 0.04 mrem (mrem is the standard unit of radiation exposure) from the whole body; 3.7 mrem (average adult) each from the hip and spine and 0.2 mrem from the forearm. In comparison, a typical airplane flight from Columbus to Los Angeles would expose your whole body to about 30 mrem of radiation and the annual natural exposure of radiation in Columbus is about 300 mrem per year. Any dose of radiation could be potentially harmful, but the risks that you will be exposed to are so small that they are difficult to measure. If you have had more than 5-10 x-ray procedures in the last year, you should discuss this with the investigator.

DEXA scans expose your body to radiation. Although it can vary from person to person, your whole-body radiation exposure is equivalent to approximately 3% of the amount of exposure a person in the U.S. receives from natural background radiation. The risk of harm from this amount of radiation is low and no harmful health effects are expected; however, your risk of harmful effects may increase if you are exposed to more procedures that involve radiation.

Dual energy x-ray absorptiometry (DEXA) scans will expose you to a low dose of radiation, comparable to the radiation experienced during a airline flight across the United States. Although the dose is low, the radiation could cause birth defects in unborn babies. If you are a female capable of having a child, then you may be asked to take a urinary pregnancy test on the morning of the DEXA measurement to confirm that you are not pregnant.

You may experience a small amount of discomfort while being placed on the examination table or while lying down for the test. This discomfort will be minimized by keeping the time involved in making the measurements as short as possible, and by allowing you a break if necessary.

Sagittal abdominal diameter

Procedure: The **Holtain-Kahn Abdominal Caliper** will be used to measure the anteroposterior (front to back) depth or thickness of your body at the level of the iliac crest (hip). The subject will lie on a flat surface with hips flexed and with the bottom arm of the portable device placed under the back so that the upper arm edge runs across the abdomen at the level of the iliac crest. The upper arm of the Holtain-Kahn Caliper, which slides up and down on the vertical arm, is then allowed to rest on the subject's abdomen while a measurement from the scale on the vertical arm is taken after the subject breathes in and out.

Procedure: The depth or thickness of your body will be measured at about the area where your stomach joins your hips. You will lie on a flat surface (bed) and one arm of this measurement device will be placed under my back while the top arm will rest on your stomach and the scale of numbers will be read as you inhale and exhale gently.

Skinfold measurement

Procedure: The thickness of your skin will be measured at two sites on your body: the back of your arm (triceps), and then just below your shoulder blade (subscapular).

The Lange Caliper will be used to measure the thickness of fat just below the skin and then calculate body density and percent body fat. In following standardized procedures and techniques, measurements will be taken three times at each site on the right side of the body using the thumb and index finger grasping the skinfold. Six [whatever number!] sites on your body will be measured using this technique.

To make taking these measurements easier you will need to wear light, loose-fitting clothing without metal buttons or zippers. You may also change into a hospital gown, if you would prefer. From this information the researchers will be able to calculate the approximate percent of your weight that is lean mass or fat mass.

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 exhausted]. During the test, your heart rate, blood pressure and oxygen level will be monitored and you will be asked to rate your perceived level of exertion by pointing to a standardized chart. If you feel faint or uncomfortable, then you can request that the exercise test stop.

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.

Endocrine Studies

Mixed meal test (24 hour meals profile)

Procedure: This test will allow researchers to measure what foods do to the body and how foods are utilized by the body. For this procedure you will be admitted to the [insert name of the clinical research facility, e.g., The Ohio State University Clinical Research Center] on the evening prior to the test [or early in the morning on the day of the test (6:00am)]. You will be required to *not* eat anything for 10-12 hours *prior* to the test. At 7:00 am on the day of the test, the nurse will insert two (2) intravenous (IV) lines (plastic tubes used to draw blood) into the veins (blood vessels that carry blood to your heart in the body) in your arms (one in each arm). Blood samples will be drawn [at – insert time point(s)]. You will be asked to consume a standard [Healthy Choice] breakfast at 8:00am, lunch meal at 12pm, and dinner meal at 6pm. Blood samples will be drawn every XX minutes from 7:30 am until 8am the next day (24 hour profile) to measure the concentrations of various chemicals in your blood.

Risk: The mixed meal is a standard prepared meal. There are no known risks to eating this meal; however, it is possible that you may not like the type of foods and/or the taste of those foods included in the meal.

Oral Glucose tolerance test:

Procedure: On the night before your test, you should not eat or drink anything for 10-12 hours. A thorough history and physical examination will be performed by one of the physicians involved in the study before this test is conducted.

After the consent has been signed a nurse will instruct you to lie on your back comfortably in a bed. An intravenous (IV) line (plastic tube used to draw blood) will be inserted into your arm.

The nurse will draw blood samples for various chemicals in the body [glucose (sugar in the blood), insulin, c-peptide (hormones produce by the pancreas), cholesterol, fatty acids (fat in the blood) and adiponectin levels]. [You also will have blood samples obtained to measure substances derived from fat cells that have been associated with type 2 diabetes, high blood pressure and heart disease]. The nurse will then give you a sugar substance to drink over a 2 minute period. Blood samples will be drawn every 30 minutes for 180 minutes.

Risks: You may find it difficult to drink the extremely sweet glucose [sugary] liquid. Some people feel sick after drinking the glucose liquid and may vomit. Vomiting may prevent you from completing the test on that day.

The blood sample is taken from a vein in your arm. An elastic band is wrapped around your upper arm. It may feel tight. You may feel nothing at all from the needle, or you may feel a quick sting or pinch. You may feel faint from having several blood samples taken in one day. However, the amount of blood taken should not cause significant blood loss or anemia.

It is possible that your blood glucose levels may drop very low toward the end of the test. Symptoms of low blood glucose include weakness, hunger, sweating, and feeling nervous or restless. If you develop these symptoms during the test, you may have your sugar level checked quickly with a glucose meter. If your level is very low, the test will be stopped.

Frequently Sampled Intravenous Glucose Tolerance Test (FSIVGT)

Procedure: The frequently sampled intravenous glucose tolerance test or FSIVGT, is a test that measures how well your body responds to a high dose of intravenous (IV) glucose and insulin. You will not eat or drink for 10-12 hours the night before the test. You will report to the [insert name of research facility, e.g., The Ohio State University Clinical Research Center]. Your nurse will explain the procedure to you. You will be instructed to lie flat in bed on your back. The nurse will insert two (2) intravenous (IV) lines (plastic tubes for drawing blood) into your veins (blood vessels that carry blood to your heart in the body) one in each arm. The nurse will draw four (4) tubes of blood over 20 minutes. After this, the nurse will give you an IV injection of glucose. After 20 minutes, the nurse will inject insulin into the IV line. Blood samples will be collected at frequent times over a 180 minute period - (total of 20 tubes). There will be about 10 milliliters of blood per tube or $20 \times 10 = 200$ milliliters of blood. In addition 1 ml of blood will be discarded per blood draw (20 ml). Total blood volume = 220ml of blood. This is equal to approximately 15 tablespoons of blood.

You will receive a Frequently Sampled Intravenous Glucose Tolerance Test (FSIVGT). This test will assess your body's ability to respond to intravenous (IV) glucose and insulin. You will have two intravenous catheters (IVs) placed in your arm. You will have a sugar solution and insulin injected into your veins through one IV. These solutions will change the glucose (blood sugar) level in your blood. Blood samples for glucose and insulin [and C-peptide (hormones produced by your body)] will be drawn from the other IV to measure how your body uses glucose and insulin. Blood will be drawn a total of 19 times during the FSIVGT. During this test a total of approximately 6.5 ounces or about $12 \frac{2}{3}$ tablespoons of blood taken.

Risk: The discomforts associated with the study will be those associated with the FSIVGT include blood drawing and intravenous catheter (IV) placement. There is potential for pain, bleeding, fainting, bruising, infection and/or hematoma (blood clot under the skin) at the IV site. This is temporary and can be treated with warm compresses and/or antibiotic medication, if necessary. These risks will be minimized by using well trained and experienced medical personnel. There is a risk involved with the injection of insulin through the vein. This can lead to the blood sugar dropping too low. This will be treated if and immediately when it occurs. The symptoms associated with blood sugar that is too low are dizziness, confusion, sweatiness, irritability, and the sensation of heart racing. These symptoms go away with the appropriate treatment and will not cause any permanent problems, because the low blood sugar will be treated immediately.

Clamp studies

Procedure: Euglycemic Clamp and indirect calorimetry allows researchers to 1). examine whether insulin directly affects adiponectin levels, 2). examine the relationships between adiponectin on carbohydrate, fat and protein utilization and, 3) examine the effects of insulin on adiponectin and gene expression in the skeletal muscle and fat tissue. During this procedure you will lie flat on your back in a bed. A nurse on the [insert name of research facility, e.g., The Ohio State University Clinical Research Center] will explain the procedure to you. Your nurse will insert two (2) intravenous (IV) lines (plastic tubes used to draw blood) into the veins (blood vessels that carry blood to your heart in the body) in your arms (one in each arm). One IV line will be to draw blood the other to give medication. You will have a plastic, transparent dome placed over your head by your nurse while you lie flat in bed. This dome will be connected to a machine that will allow the researchers to measure the amount of oxygen you breathe in and out. When the test begins, one of your hands will be placed in a “warm box”. The purpose of the warm box is to keep your blood temperature constant throughout the test. You will be asked to lie quietly for 20-30 minutes. After this “resting” period the test will begin.

The nurse will then give you an IV glucose solution that contains a substance that allows the amount of glucose in your blood called D3-3H glucose or tritiated glucose, to be measured. The amount of radiation in tritiated glucose is equal to that of a chest x-ray. This substance will allow the researchers to measure the rate at which glucose appears and disappears in your blood. This solution gets slowly broken down in your body and then leaves the body through the urine within 24 hours. Both insulin and glucose will be administered throughout the study. You will be given another medication in your IV line called Sandostatin. This medication will slow down or stop the natural production of insulin in your body. The nurse will monitor your blood frequently and make adjustments in the level of glucose that enters into your bloodstream through the IV line. The IV insulin will be delivered at a constant rate for 120 minutes. The blood glucose will be measured at the bedside at frequent intervals to adjust the levels of the glucose infusion. Blood samples for glucose, hormones secreted by your pancreas (c-peptide, glucagon and insulin) and free fatty acid will be taken at 20 minute intervals for 240 minutes. Approximately 10 ml of blood per tube or $24 \times 10 = 240$ ml of blood will be kept for research tests. There will be 1 ml of

blood discarded per blood draw (24 ml). The total amount of blood drawn that will be drawn will be about 264 ml. This is approximately 18 tablespoons of blood.

A procedure called a **glucose clamp** will be conducted during the study. During a glucose clamp insulin and sugar are given into one intravenous catheter (IV) and blood is drawn every 5 min through the other IV to determine how much sugar is in your blood. Two different rates of insulin will be given during the clamp. The first will be a low dose and the second a high dose. Each dose will be given for 150 min. The amount of sugar given will be adjusted to keep your sugar normal for the entire time. Every 30 minutes the blood pressure cuffs will be inflated to measure how much blood is going to your arm. During the study visit a maximum of 10 tablespoons of blood will be taken.

Risk: Having intravenous catheters (small plastic tubes) placed in your arm(s) may cause pain, bruising, and infection.

The tests to measure blood flow and blood vessel function may cause discomfort, numbness, or tingling in the hand or arm. If this is too bad the study will be stopped.

Giving insulin and sugar water may cause your blood sugar to go to low or to high. High blood sugar will make you urinate more and thirsty. Symptoms of low blood sugar are sweating, shaking, anxiety, hunger, and confusion. . If the sugar level goes too low coma and seizure, brain damage, and death are possible. Rarely, someone may have an allergic reaction to the insulin. Should your blood glucose levels go too high or too low, medical treatment will be immediately available.