COMIRB
APPROVED
For Use
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**Principal Investigator: Bryan Bergman, PhD**
**COMIRB No: 16-1404**
**Version Date: 07/19/18**

**Study Title: Skeletal muscle diacylglycerol and sphingolipids – impact of localization and species on insulin resistance in humans**

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

### Why is this study being done?

This study plans to learn more about how fat stored in muscles is related to diabetes.

You are being asked to be in this research study because you are overweight and are interested in losing weight or becoming more physically fit.

### Other people in this study

Up to 92 people from your area will participate in the study.

### What happens if I join this study?

If you join the study, you will be asked to perform 2 screening visits and two metabolic studies. About a week after the first screening visit, you will come in for a second screening visit. One metabolic study is done before and one after either A) a weight loss intervention, B) an exercise training intervention, or C) normal living (delayed intervention control – you will have the option to do either intervention A, B, or a combination weight loss and exercise training intervention when you finish). These visits take place at the Clinical Translational Research Center (CTRC) at the University of Colorado Denver, Anschutz Medical campus. It will take approximately 5 months to complete the visits for this study.

These tests are described in detail below.

### Screening Visit #1

You will be asked to come to the outpatient clinic of the CTRC for a screening visit to make sure you are healthy enough to participate. You must not eat or drink anything (except water) for 10-12 hours before you arrive. A physician will give you a detailed

physical examination to confirm that you are in a good state of health. You will also be asked details on your previous medical history and family medical history. About 2 tablespoons of blood will be taken from your arm to look at the function of your liver, thyroid, and kidneys, and your blood sugar and lipids. You will be asked to provide a sample of urine for testing including a pregnancy test in females. This examination will take about 20 minutes.

Female volunteers may or may not be using hormonal contraception during the duration of the study. Please don't change contraception method during the study. Female volunteers must not have gone through menopause to participate.

We will ask you to fill out a paper and computerized diet questionnaire so that we can estimate what kind of food you eat in your normal diet. You will also be asked to complete a questionnaire about your physical activity.

The total time for the screening visit will be approximately 1 hr.

You will be provided a snack before you leave.

Screening Visit #2

**Muscle Strength Test**

If you qualify for the study based on results from the screening visit, we will measure your leg strength using a leg strength machine. We will ask you to sit on a chair, and extend your lower leg against a bar to measure muscle strength. We will make several measurements at half maximum effort to familiarize you with the protocol and provide a warm-up. Three maximal efforts will then be performed to measure maximal leg strength. This test takes about 10 minutes.

**Exercise Test**

After the muscle strength test, we will determine your heart function and fitness level using an exercise treadmill test. We will ask you to change into exercise clothes, and will place electrodes on your chest to monitor your heart function during the exercise test. You will have a blood pressure cuff on one arm so we can measure your blood pressure during the test. We will then place a mouthpiece (scuba style) in your mouth so that a machine can measure how much oxygen your body is using during the exercise test. A nose clip will be placed on your nose so that you can only breathe into and out of the mouthpiece. You will warm-up for a few minutes on the treadmill, then the test will begin, becoming harder as the treadmill will increase 2% in steepness every 2 minutes until you cannot go any more, or the physician stops the test. We will ask you to point to how you are feeling on a chart every 2 minutes. The speed of the treadmill stays the same throughout the test. A physician will be with you during this test, and may choose to stop the test if your heart shows an abnormal beating pattern or blood pressure. This test takes about 30 minutes.

After each test, a physician will read the heart function test to rule out heart problems. If

the test suggests you have a heart problem, you will be referred to you heart doctor for further studies at your own expense. You will be allowed to re-enter the study with a note from your heart doctor saying you are healthy to continue.

**Body Composition Test**

For all individuals in the study we will measure the amount of fat and lean tissue in your body using a low-dose x-ray machine, called the DEXA. This will happen after finishing the exercise test. You will be asked to lie down on the raised platform or "bed" of the DEXA machine. An arm attached to the machine will move up and down the length of your body. The arm rests about 1 foot above you. The measurement will take 10-12 minutes during which time you must lie completely still. The total time for this test is approximately 30 minutes.

**MRI Test**

After the body composition test, we will also measure the amount of muscle and fat in your leg, as well as the amount of fat in your liver. You will be asked to lie down on a raised platform and wear headphones to protect your ears. The platform will then be moved into a small tube where a strong magnetic field will be used to take pictures of your body. The measurements will take approximately 15 minutes during which time you must lie completely still. The total time for this test is approximately 30 minutes.

**Maximal Mitochondrial Respiration test**

We will also measure maximal mitochondrial respiration non-invasively. You will be asked to lie down on a table, and we will strap a small plastic box to your leg. This box uses a laser to measure the oxygen levels in your muscle. We will also wrap a blood pressure cuff around your upper thigh. To start the test, you will be asked to make a muscle contraction for 20 seconds, after which we will intermittently inflate and deflate the blood pressure cuff every 5-10 seconds over a 5 minute period. This test will then be repeated. The total time for this test is 30 minutes.

**Pickup Actiwatch**

During this visit you will also pickup the Actiwatch, a small device worn on your wrist that will continuously monitor your activity and light exposure. The wrist activity recorder is the size of a watch. You will be asked to wear it all day and night for the rest of the study, but please remove it for showering and swimming.

The total time for this visit (strength and exercise testing, body composition, and MRI) will be approximately 3 hrs.

This study will have 3 different groups of research subjects like you. To decide which group you are in, we will use a method of chance. This method is like flipping a coin or rolling dice. You will be assigned to either A) a weight loss intervention, B) an exercise training intervention, or C) normal living (delayed intervention control – you will have the option to do either intervention A, B, or a combination weight loss and exercise training intervention when you finish).

## Metabolic study day

Controls prior to study day:
For 3 days prior to each metabolic study, you will receive all of your food from the investigative team. It is important that you eat only the food that you receive from the investigators. The diet will consist of foods you like and will be designed to provide food very similar to your normal diet. The calories you will be given will be calculated to maintain your body weight. You will only pick up food one time during the three-day dietary control. You will then take a soft-sided cooler containing your food to eat when you like. Please maintain your normal planned physical activity during the first 2 days of diet control. On the last day of the diet (day three, the day before the metabolic study) you will be asked not to perform any planned exercise other than that involved in your daily routine. Women will be studied during the first 10 days after starting their period.

Evening before study:
Arrive to the CTRC between 8-9pm, after eating dinner between 7-8pm, and stay the night on the CTRC. During your stay we will ask you to complete some questionnaires about your sleep patterns and your sleep patterns will be monitored by recording your brain waves. To do this we will wash portions of your skin with special soap and cleanse the skin with an alcohol swab. Small sensors will be placed on the skin of the scalp, face, chin, upper chest and stomach, some of which are held in place by a special medical glue or tape. These sensors will be used to record the electrical activity of your brain (EEG-brain waves), eye movements (EOG-when your eyes look left, right, up and down), muscle activity (EMG-muscle movements of your chin), and heart rate activity (ECG-your heart tracing). We will also measure your breathing. To do this, a sensor placed across your nose and mouth will measure airflow by detecting the temperature of the air as you breathe in and out. Elastic bands fitted around your chest and abdomen will be used to measure movement of your chest. A sensor that shines a red light onto your finger will measure oxygen levels in your blood. In addition to these breathing measurements, sensors will also be placed on your legs to measure leg movements while you sleep.

Morning of study – 5:30am:
A hollow needle/plastic tube will be placed in a vein on the inside of your right forearm. Another hollow needle/plastic tube will be placed in a vein on the surface of your left hand. The hollow needle/plastic tube in the right arm will be used to put 1 solution in your body: a non-radioactive, naturally occurring glucose isotope that can be tracked in your body. The hollow needle/plastic tube in your left hand will be used to withdraw blood during the study. We will take approximately 1 cup of blood during the study. This study will take approximately 6 hours during which time you cannot eat food.
6:00am
We will place your left hand in a heating pad that is heated to above body temperature (air temperature of 144-153°F inside).
6:20am
Half a tablespoon of blood will be taken from this hand to measure the amount of

traceable glucose in your blood from the foods you eat, and your naturally occurring hormone levels.

6:30am

We will start an infusion of stable, non-radioactive, naturally occurring isotope of glucose which will continue throughout the study. We will ask you to lie quietly throughout the day until 12:30pm (you can fall asleep, read, or watch TV if you like).

8:00am, 8:10am, 8:20am, 8:30am

4 tablespoons of blood will be taken from the hollow needle/plastic tube in your hand for our metabolic analyses.

8:30am

A physician or physician's assistant will perform a muscle biopsy on your leg (mid-thigh). The muscle biopsy will consist of injecting some numbing medicine into the skin on your thigh to reduce the pain, then making a small hole through which we can remove a small piece of tissue (approximately 150 mg – about the size of an eraser head on a number 2 pencil). The biopsy site will be closed with tape and a pressure bandage. The biopsy will take about 15-20 minutes.

9:00am

Immediately after the biopsy is finished, we will start a 3 hour insulin clamp. During the insulin clamp we infuse insulin (a natural hormone that causes your body to absorb sugar) and glucose to keep your blood sugar constant at a normal level. Every 5 minutes we take a 1/4 teaspoon of blood to make sure your sugar levels are in the normal range.

10:00am

A physician or physician's assistant will perform a muscle biopsy on your other leg (mid-thigh). The muscle biopsy will be performed exactly like the first one, but in your other leg.

11:00pm

We will put a plexi-glass hood over your head for 15 minutes to measure the oxygen and carbon dioxide content of your breath to determine your metabolic rate.

11:30am, 11:40am, 11:50am, 12:00pm

We will withdraw 4 tablespoons of blood from the hollow needle/plastic tube in your hand for our metabolic analyses.

12:00pm

After the clamp is finished, we will stop the insulin clamp and provide a meal for you to eat.

After completing this metabolic study, you will then be asked to start the intervention to which you were assigned

Weight loss only intervention

After the first metabolic study, you will then start a low calorie diet for 12 weeks with a goal of losing 8-10% of your baseline body weight. For a 200 pound person, this would be about 16-20 pounds. To help you lose weight, we will provide you with meal replacements. The meal replacement is low calorie, high protein and provides all the vitamins and minerals your body needs. It will replace your traditional meals and provide

structure to help you lose about three pounds per week. The meal replacement can be used in recipes so it is not all liquid meals. You will learn how to use the meal replacement at a one hour meeting at the Health and Wellness Center before you start your weight loss. In addition to the meal replacements you can also eat 4-5 servings of fruits and vegetables per day. You should also consume 2 teaspoons ofvegetable oil each day to prevent gallstones. This will total about 1100 calories per day for your energy intake.

While losing weight, you will check into the Health and Wellness Center every other week for follow up to be weighed and to assess your progress. At this time you can pick up your meal replacement product. During this visit to the center you will participate in the mandatory educational/ behavioral session led by trained professionals. You will have your weight measured and recorded by the staff and will have your blood pressure checked, as needed. If weight loss progress slows before reaching the goal then the frequency of visits will increase. During the weight loss phase, you need to eat all of your meal replacements (4 or 5 depending on your plan), fruits and vegetables (4-5 servings per day if part of your plan), and fluid (3 quarts) to be nutritionally safe and achieve predicted weight loss. You are required to drink a minimum of three quarts of non-caloric fluid daily, two quarts of which must be water. Failure to consume the minimum amount of meal replacements and fluid may be harmful to your health. The staff reserves the right to terminate your participation in this program due to failure to consume the minimum required foods and fluids. Consuming alcohol and using illegal drugs while on a low calorie diet is unsafe and you must agree to abstain.

You must attend both the medical and educational component of the program each week at the Health and Wellness Center, except for emergency reasons. If an emergency arises and you must be absent from the designated attendance time, you will contact your program leader to reschedule an appointment during available clinic hours.

Once you have reached the goal weight loss, you will then maintain your weight for a minimum of 2 but no more than 4 weeks prior to the post-intervention metabolic study. Your weight should not change by more than about 3 pounds during this time. You will be seen by study personnel on a weekly basis during this time.

After the weight loss intervention is finished, you will have access to the Exercise Research Lab for 12 weeks in order to perform exercise training. This is completely optional, but we want to provide access to exercise equipment to help maintain your weight loss.

Exercise training only intervention

You will be asked to participate in a supervised exercise program at the Exercise Research Lab (ERL) for 12 weeks. The exercise program will include cardiovascular types of exercise, with supervised exercise performed 4 days/week, as well as 1 day/week on your own, exercising 45-60 minutes/day. You will be able to come during

any of the three sessions that we offer Monday-Friday (6:30-8:30) (11:30-1:30) or (4:30-6:30) to complete your exercise. During this exercise training intervention you need to keep your weight stable. This means that you will need to eat approximately 200-400 extra calories each day. You will be weighed each week during training to make sure you aren't losing weight. If weight loss occurs, we will meet with you to talk about nutrition to regain the weight and prevent further weight gain.

Half way through the exercise training during week 6, we will repeat the same treadmill exercise test that was done during your screening visit. This will involve walking or running on a treadmill for about 10-15 minutes while you breathe through a special mouthpiece. As before, the exercise will be easy at first, but will gradually become more difficult until you can no longer continue. This test is done to measure your fitness.

After the exercise training intervention is finished, you will be eligible to join a weight loss intervention that we provide for 12 weeks. This is completely optional, but we want to help you lose weight after becoming more fit.

Control (delayed intervention)
You will be asked to maintain your normal nutrition and exercise habits during the 12 week intervention. It is very important to not change your amount of planned physical activity and to not lose weight. After the intervention is complete you will have the option to do either the weight loss intervention, exercise intervention, or a combination weight loss and exercise training intervention for 12 weeks when you finish.

**After completing the intervention, within one week you will be asked to repeat the muscle strength test, treadmill exercise test, the DEXA test for body composition, MRI, and maximal mitochondrial respiration test. You will also be asked to repeat the 3 days of dietary control, overnight CTRC stay with sleep recording, and the pre-intervention metabolic study including the insulin clamp, and muscle biopsies within 2 weeks of completing the intervention.**

**What are the possible discomforts or risks?**

Discomforts you may experience while in this study include the following:

**Risks of Having Blood Taken**
In this study we will need to get about 2 tablespoons of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

**Risks of Having An IV Inserted In Your Vein**

In this study we will insert a needle, connected to a plastic tube, into each forearm during both metabolic studies. We will use the tube to take blood samples or give you fluids. You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling, or bruising where the tube goes under your skin. In some cases, this type of tube can cause an infection where it goes under the skin. In rare cases, it can cause a blood clot in the vein. You will have this tube inserted for about 7 hours. A total of ~250ml of blood will be taken from the subjects during the study in aims 1 and 2. This is approximately 5% of total blood volume and is not associated with a risk of anemia.

**Risks of Muscle Biopsy**
In this study we take a small sample of muscle tissue from you. This procedure is called "muscle biopsy." Before we take the tissue samples, we will numb the skin. We will then make a small cut in the skin and insert a hollow needle. You may feel discomfort when we inject the numbing medicine (the anesthetic) but during the actual muscle removal, the discomfort should be minimal. There is a risk of infection, muscle cramp, bleeding, bruising, and nerve damage. The risk of infection, muscle cramp, bleeding, and bruising can be minimized if you follow the instructions for caring for the incision. A very small and minor scar may remain as a result of the incision. You could also have an allergic reaction to the numbing drug. You will be screened prior to the procedure for history of allergic reactions to the numbing medicine (e.g., lidocaine).

**DEXA Risk**
As part of this study we will perform 2 DEXA scans of your entire body. DEXA is a way of looking inside the body by using X-rays. X-rays are a type of radiation. Your natural environment has some radiation in it. This DEXA will give you about the same amount of radiation that you would get from your environment in 4 days.

**Risk of muscle strength testing**
You may experience muscular discomfort during the strength test. Your leg may be sore the day after the muscle strength test.

**Risk of maximal mitochondrial respiration test**
You will experience frequent tightening of the blood pressure cuff on your leg, which may be uncomfortable.

**Risk of having an MRI**
In this study we will take Magnetic Resonance Images (MRI's) of your legs and liver. The MRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working.

**You should NOT have an MRI if you have <u>metal</u> or <u>electronic devices</u> inside your body. Heart pacemakers and insulin pumps are examples of electronic devices.**

The MRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces.

The most common side effect of having an MRI is flashing lights in the eyes. This is caused by the magnetic waves and is not harmful. Some people also experience warmth and reddening of the skin. This usually goes away after a few minutes.

**Risk of Exercise Test**
During the exercise testing and training you may experience a fall, as well as discomforts such as pain in your muscle or joints. During the exercise testing and training you may feel dizzy or faint as well as experience irregular heartbeats, a stroke or heart attack. The risk of death during or immediately after an exercise test is less than 1 in 10,000. The risk of a heart attack during or immediately after an exercise test is less than 4 in 10,000. The risk of a problem that would require hospitalization, such as chest pain, is less than 2 in 1000.

**Risk of Sleep Recording**
Measurement of the electrocardiogram (ECG-heart tracing) may cause some skin irritation from the sensors. Measurement of the electroencephalogram (EEG-brain wave activity), Electroocculogram (EOG-eye movement activity) Electromyogram (EMG-muscle activity on the chin and legs), nasal-oral air thermister (breathing in and out of the nose & mouth), and respiratory bands placed over the chest and abdomen, may cause some minor discomfort and/or skin irritation due to the paste used to attach the sensors. In addition, the paste used to hold sensors to the scalp may leave a flaky residue for several days.

**Risk of Weight Loss**
During the weight loss phase, you could experience one or more of the following: bowel changes, cold sensation, and menstrual irregularities. Not everyone will have these side effects. Adding other foods, not part of the meal replacement plan, could have side effects such as stomach cramping, diarrhea and lack of predicted weight loss. During the weight loss phase, you could experience one or more of the following: dizziness or lightheadedness, fatigue, dry skin, and some temporary hair loss. Not everyone will have these side effects. Eating high fat foods while on the low calorie diet has additional risk of triggering an acute gallbladder attack. Some research studies have found that during a low calorie diet, there is an increased risk of gallstone formation or gallbladder disease. During the weight loss phase, you could experience temporary anemia (which may make you feel weak or tired). Not everyone will have this side effect.

**Risk of Insulin Clamp**
The heating pad in which your arm is placed on the study day may be uncomfortable, and it can feel like a sauna. Resting metabolic rate testing may make you feel claustrophobic when the clear plexiglass hood is placed over your head to collect your expired breath. The solutions prepared for infusion are sterile and present no risk. They are not associated with allergic responses as they are substances normally present or

produced in the body. The infusions are also tested to be free from substances that could cause a fever. There is a risk of having low blood sugar during the insulin clamp. However, we will measure blood sugar every 5 minutes during the clamp to prevent this from happening. The insulin clamp carries a 1 in 10 risk for symptoms of hypoglycemia (neuroglycopenic or autonomic), and less than 1 in 10,000 of serious sequellae of hypoglycemia such as seizure, coma or death.

**Risk of losing confidentiality**

Violation of privacy and loss of confidentiality are both risks to which research participants are exposed. The possibility of these risks increases when protected health information is collected.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

**Certificate of Confidentiality**

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

**What are the possible benefits of the study?**

This study is designed for the researcher to learn more about diabetes.
However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are listed in the section describing the discomforts or risks.

**Who is paying for this study?**

This research is being sponsored by the National Institutes of Health.

**Will I be paid for being in the study?**

You will be paid $25 for completing both the screening visit and the exercise testing/body composition visit. You will be paid $150 for completing the first metabolic study, and $325 for completing the intervention and the second metabolic study. This will add up to a total of $500 if you complete both visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

**Will I have to pay for anything?**

It will not cost you anything to be in the study.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

**Can I be removed from this study?**
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

**What happens if I am injured or hurt during the study?** If you have an injury while you are in this study, you should call Dr. Bryan Bergman immediately. His phone number is 303-359-2028.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

**Who do I call if I have questions?**

The researcher carrying out this study is Dr. Bryan Bergman. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Bryan at 303-724-3919. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Bryan Bergman with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055. You can also talk to a Subject Advocate at the Clinical Translational Research Center (CTRC). The phone number there is 720-848-6662.

**Who will see my research information?**

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

*Dr. Bryan Bergman*
*University of Colorado Denver*

*MS 8106*
*Aurora, CO 80045*

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The National Institutes of Health, who is paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make some of the following health information about you collected in this study available to:
• Eli Lily lipidomics laboratory
• Helmholtz Zentrum Muenchen laboratory

**Information about you that will be seen, collected, used and disclosed in this study:**

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Research Visit and Research Test records
- Tissue samples and the data with the samples.

**What happens to Data, Tissue, Blood and Specimens that are collected in this study?**

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, or the tissue, blood, or other specimens is given by you to the investigators for this research and so no longer belongs to you.
- Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

**Optional Consent for Data and Specimen Banking for Future Research**

Dr. Bryan Bergman would like to keep some of the data, blood and tissue that is taken during the study but is not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about obesity and type 2 diabetes. The research that is done with your data and samples is not designed to specifically help you. It might help people who have type 2 diabetes and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Bryan Bergman keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Dr. Bryan Bergman to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Bryan Bergman decides to destroy them.

When your data and samples are given to other researchers in the future, Dr. Bryan Bergman will not give them your name, address, phone number or any other information that will let the researchers know who you are.

The possible benefits of research from your data and samples include learning more about what causes obesity, type 2 diabetes, and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Bryan Bergman will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Bryan Bergman.

Please read each sentence below and think about your choice. After reading each sentence, circle “yes” or “no.” If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

I give my permission for my data, blood and muscle to be stored in a central tissue bank at The University of Colorado Anschutz Medical Campus for future use by the study investigators:

1. I give my permissions for my data, blood and tissue samples to be kept by Dr. Bryan Bergman for use in future research to learn more about how to prevent, detect, or treat obesity and/or type 2 diabetes.

   ☐ Yes ☐ No _____Initials

2. I give my permissions for my data, blood and tissue samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis).

   ☐ Yes ☐ No _____Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   ☐ Yes ☐ No _____Initials

**HIPAA Authorization for Optional Additional Study Procedures –**

In this form, you were given the option to agree to banking of data in a recruiting database. You must also give us your permission, under HIPAA rules, to use and disclose this information, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in the recruitment database, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedure I have agreed to above, to be used and disclosed as described in this section.

___ I do not give permission for my information for any optional procedure to be used and disclosed; I understand that I will not participate in the recruitment database.

## Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____

Investigator must sign within 30 days