

Consent Form Approval

Date:

Valid for Use Through:

Study Title: Regional fat re-accumulation in pre- and postmenopausal women following lipectomy

Principal Investigator: Rachael Van Pelt, PhD

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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?

You are being asked to participate in a research study of women undergoing liposuction in the lower body (hips and thighs). The goal of this study is to see where the fat you eat in a meal (dietary fat) is stored after thigh fat tissue has been removed by liposuction. Because thigh fat is a good place to store dietary fat, it is possible that any fat you eat will remain in your blood longer or get stored in other places in the body. This research study will try to answer these questions.

Other people in this study

You are being asked to participate because you are a healthy pre- or postmenopausal woman between the ages of 35-60 yr who would like to have liposuction of the hip and thigh area. We will enroll up to 170 women in this study.

What happens if I join this study?

If you agree to take part in this study, we will ask you to do the following things over the course of 14 months at the University of Colorado Hospital and Clinical Translational Research Center (CTRC). Your care will include the following visits and procedures.

- ❖ **A physical examination and medical history** will be done by a study physician or nurse involved in the study at one of your screening study visits. The physical exam and completion of medical history forms will take about 45 minutes. We will check your resting heart rhythm using an EKG during this exam. We will also ask you questions about your body weight and history of managing your body weight. There is no right or wrong answer to these questions; they simply help us evaluate how you feel about your body.
- ❖ **Standard blood and urine tests** – this will take about 15 minutes and will involve taking approximately 3 Tablespoons of blood. The blood tests measure electrolytes, liver and kidney function, thyroid stimulating hormone (TSH), blood cell count, blood sugar, cholesterol, triglycerides. You will also be asked to take a urine pregnancy test if you are premenopausal.
- ❖ **Glucose tolerance test** – this test determines how quickly your blood sugar (or glucose) levels return to normal after you drink a solution containing sugar. A needle with a plastic sleeve will be inserted in a vein in your arm. The needle will be removed, but the plastic sleeve will remain in place so that multiple blood samples can be obtained without inserting a needle each time. You will

drink an 8-ounce solution containing sugar. Blood samples will be obtained immediately before you drink the solution, and 30, 60, 90, and 120 minutes later. Extra blood will be taken in the first sample so that we can also measure your blood cholesterol. Approximately 6 Tablespoons of blood will be collected during this test.

Randomization - You will be invited to take part in this study if all of the above screening tests are within normal limits and you meet the guidelines for entry. The surgeon must also agree that you are a good candidate for liposuction. If you agree, you will be randomly placed into either a surgery group or control (delayed surgery) group. Random placing occurs by chance, like the flip of a coin. Neither you nor we have control into which group you end up. You will have equal chance of ending up in either group. However, surgery is available to both groups. The surgery group will have surgery at the beginning of the study and the control group can have surgery at the end of the study.

- ❖ **Body composition** – We will measure total body fat using a machine called a DEXA and we will measure belly and thigh fat using CT. These tests will require lying still on a table for about 10 minutes for the DEXA scan and 30 minutes for the CT scans. We will also measure your arm, bust, waist, hip, and thigh circumferences using a tape-measure. This will take about 10 minutes.
- ❖ **Test meal** – This test will allow us to study where the fat you eat in a meal is being stored in your body. We will ask you to eat a standard diet that we provide for the 5 days leading up to the test. The morning of the study you will be admitted to the CTRC and given a liquid meal to drink. This drink will have a fat tracer mixed in it that we can then measure in your blood and fat tissue. We will take a small sample of blood before and then at 30, 60, 120, 180, 240, 300, and 360 minutes after the meal. About 1.5 cups of blood will be collected during this 6 hour test. Before the meal and for 15 minutes each hour we will also place a clear plastic canopy over your head to measure how many calories your body uses at rest and after a meal. We will also have you breath into a tube to collect breath samples each hour and to give us a urine sample to measure how much fat your body is using. After this 6 hour test we will ask you to remain at the CTRC until the next morning when we complete the test by taking a sample of your fat from the belly and the thigh. We will take additional breath samples 3 more times during this study visit (at 9, 14 and 24 hours after the test meal).
- ❖ **Fat biopsies** – Twenty four hours after the test meal fat biopsies will be done to remove a small sample of fat from your thigh and belly. At the 2-month visit fat biopsies will be taken before the test meal as well. First, you will be given a medicine (lidocaine) under the skin to numb the area. After the area is numb you may feel pressure but should not feel pain. A small cut in the skin is then made from which the fat will be removed using a syringe. After the fat is removed, the doctor will place thin strips of tape to close the small cut.
- ❖ **Weight maintenance/ 4-day diet period** – For the 4 weeks leading up to the test meal we will ask you to maintain your body weight to the best of your ability. We will ask you to record your food intake and physical activity (described below) during the first week and then maintain your diet and activity at that level for the remainder of the period. You will also be asked to record your body weight each of these weeks. During the 4 days leading up to the test meal visit you will be given a standard diet prepared by the CTRC metabolic kitchen. You will be asked to eat only the food provided by the dieticians and not to exercise the day before the test meal visit.
- ❖ **3-Day Food Record** - We would like you record how much and what type of food you eat for 3 days (including 1 weekend day). The CTRC dieticians will instruct you on how to complete this record. Once finished, you will return the record to the study coordinator. The record will help us understand your eating habits and how they may relate to your body fat content and metabolism.

- ❖ **Physical Activity and Health/ Well-being Questionnaires** - We will ask you to complete a form that asks you about your physical activity at work and at home. This form will help us understand how much activity you do daily and how it may relate to your body fat content and metabolism. We will also ask you to fill out 2 questionnaires that ask you about your general health and well-being and about how you feel about your body.
- ❖ **Pre-operative visit** – A day or two before the liposuction surgery you will visit with the study nurse to discuss the surgical procedure in more detail. At this visit you will be asked to sign a University of Colorado Hospital consent form specific to the liposuction surgery. We will also update your medical history with any changes that may have occurred since the initial history and physical exam.
- ❖ **Liposuction surgery** will be done at the University of Colorado Hospital (UCH, Anschutz Medical Campus) within 2 weeks of the baseline testing (surgery group only). Before surgery, you will meet with the surgeon, Christopher K. Law, M.D., who will explain the surgery and answer any questions you have. You will be asked to sign another hospital consent form before having surgery. The day of surgery, you will be admitted to UCH where you will be prepared for the operation. The surgery will be performed in the operating room while you are under general anesthesia (medicine used to put you to sleep during surgery) and is expected to take approximately 2.5 hours. Following the surgery, you will go to the recovery room until you are awake. Then, you will be admitted to the CTRC where you will be cared for by the surgeon and nursing staff for the next 24 hours.

Schedule-at-a-glance

Time point	Visit # (length)	Tests & Procedures
Before study entry/ screening visits	1 (1.5 hours)	<ul style="list-style-type: none"> • Consent form discussion, blood tests
	2 (3.5 hours)	<ul style="list-style-type: none"> • Glucose tolerance test • Medical History & Physical • DEXA Scan, circumference measures • Questionnaires
	3 (30 min)	<ul style="list-style-type: none"> • Consultation with surgeon
Weight maintenance/ 5-day diet period	Done at home	<ul style="list-style-type: none"> • 3-day food record
	4 (15 min)	<ul style="list-style-type: none"> • Food pick-up
Month 0 / Baseline testing	5 (24 hours)	<ul style="list-style-type: none"> • Test Meal • CT Scan • Fat biopsies (next morning)
	6 (1 hour)	<ul style="list-style-type: none"> • Pre-operative visit
Surgery (surgery group only)	7 (24 hours)	<ul style="list-style-type: none"> • Liposuction surgery and overnight recovery • Post-operative wound care checks with the surgeon or study nurse as needed
Month 2 follow-up testing	8 (3 hours)	<ul style="list-style-type: none"> • Glucose tolerance test • DEXA Scan, circumference measures • Questionnaires
	Done at home	<ul style="list-style-type: none"> • 3-day food record
	9 (15 min)	<ul style="list-style-type: none"> • Food pick-up
	10 (24 hours)	<ul style="list-style-type: none"> • Test Meal • Fat biopsies (pre-meal and next morning)
Month 8	11 (30 min)	<ul style="list-style-type: none"> • DEXA Scan, circumference measures

Month 14 follow-up testing	12 (3 hours)	<ul style="list-style-type: none"> • Glucose tolerance test • DEXA Scan, circumference measures • Questionnaires
	Done at home	<ul style="list-style-type: none"> • 3-day food record
	13 (15 min)	<ul style="list-style-type: none"> • Food pick-up
	14 (24 hours)	<ul style="list-style-type: none"> • Test Meal • CT Scan • Fat biopsies (next morning)
Surgery (control group only)	Optional	<ul style="list-style-type: none"> • Pre-operative visit • Liposuction surgery and overnight recovery • Post-operative wound care checks with the surgeon or study nurse as needed

What are the possible discomforts or risks?

There are certain risks and discomforts that may be associated with this research. They include:

- **Liposuction surgery** - This is a commonly performed cosmetic surgery in the US and we do not expect complications to occur during the surgery. However, as with all surgeries, there are risks. The most common risk is for infection and swelling at the surgical site. The most serious risk is death related to the surgery itself or the general anesthesia used during the surgery. Other risks include blood and fluid loss or allergy to medication, which could negatively affect the body's ability to function. Risks also include extreme drops in blood pressure or irregular heart rhythms, blood clots or increased fluid in the lungs, skin ulcers. Other problems during surgery could come from undiagnosed or unrecognized health problems.
- **Post-surgery complications** - Following surgery, you will be at risk for infection and swelling at the surgery site. To reduce these risks, you will be given antibiotics and steroids before surgery. Following surgery, you will stay overnight on the CTRC so that nurses can monitor your vital signs (blood pressure, heart rate, breathing rate, and temperature) and fluid balance and take care of your wound. You will also wear a tight-fitting garment (like a girdle) to lessen the amount of swelling in the surgical area. The surgeon and nursing staff will teach you how to care for your wound before you leave the hospital. Following your home care instructions can greatly lessen the risk of wound infection, swelling, and pain.
- **Radiation exposure** - The DEXA and CT scans that are used to measure body composition involve exposure to radiation. The amount of radiation that you will be exposed to during each DEXA scan is equal to the amount of radiation that you would receive being outdoors in Denver for about two days. The amount of radiation that you will be exposed to during each CT scan is equal to the amount of radiation that you would receive being outdoors in Denver for about one and a half months. Administration of the fat tracers in the test meal also involves exposure to radiation, about the same as you get from the DEXA scan. The total exposure to radiation from the DEXA and CT scans and the fat tracers over the 14 month study is equal to about 3 months of outdoor radiation exposure in Denver. Radiation exposure is not risk-free. We know that high levels of radiation cause cancer. This, however, does not mean that everyone exposed to these levels will get cancer. It only means that cancer incidence is higher in these populations as compared with the incidence among the less exposed. Everyone receives some background radiation, even from rocks and plants. This radiation is about 2.5% of the yearly limit recommended by the FDA. The exact increase, if any, in your cancer risk is not known. If you are or might be pregnant, you should not take part in this study to prevent your unborn child from receiving unnecessary radiation.

- **Fat biopsies** - Small samples of fat will be removed from the thigh and belly at each timepoint (Months 0, 2 and 14) during the study. It is possible that you could get an infection where the biopsy is taken (it happens about 1 out of 1,000 times). It is very rare, but you may also have an allergic reaction to the numbing medicine (less than 1 in 10,000). You may get a small scar from the biopsy. The scar is usually much smaller than the original cut and sometimes it is almost invisible.
- **Needles and catheters for taking blood samples** – A needle with a small plastic sleeve over it will be inserted in a vein in your arm and the plastic sleeve will remain in the vein for about 2.5 hours during the glucose test and for about 6.5 hours during the meal test. Inserting needles and catheters in veins can cause pain or discomfort as well as bruising or infection. These procedures will be performed using appropriate, sterile procedures so the risk of infection is very unlikely, although the risk of bruising is likely. Also, there may be some minor discomfort of having the plastic tube taped to your arm. In about 1 in 10 cases, a small amount of bleeding occurs under the skin and produces a bruise. The risk of a blood clot forming in the vein is about 1 in 100 and the risk of infection or significant blood loss is about 1 in 1000. A total volume about 2 cups will be taken for research purposes at each timepoint (Months 0, 2 and 14) during the study. This is the same amount of blood given in a blood donation.
- **Measures of calorie expenditure** - Before the Test Meal and for 15 minutes each hour for 6 hours (and again at 9, 14 and 24 hours) following the meal we will place a clear plastic canopy over your head to measure how many calories your body uses at rest and after eating a meal. Although you will be able to see through the plastic canopy and you will be allowed to breath normally, there is a chance that you will feel some claustrophobia when the canopy is placed over your head.
- **Pre- and post-surgical photos** - When you have the surgery done, we are asking your permission to take photos of you both before and after your surgery. This is being requested by the surgeon so that he can properly evaluate you at baseline and through your recovery. Taking photos of this nature is standard and routine for plastic surgery procedures. Because the photos will be taken of your lower body without clothes on, there is a risk of embarrassment or of feeling self-conscious. Every effort will be made to prevent this; you will be covered in as many areas as possible to avoid excess exposure, and your genital area will be covered entirely. Your head will not be included in the photos. The pictures will be stored according to a number code instead of by your name. Any photos taken will not be included in a publication or presentation unless you sign a separate informed consent. The photos will be kept strictly confidential by the investigators.
- **Loss of privacy/ confidentiality** - Any time personal health information is collected you are at risk of losing privacy and confidentiality. We will make every effort to protect your information.
- The study may also include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about fat storage. This study is not designed to treat any illness or to improve your health. Also there are risks as mentioned in the Risk Section. There is no guarantee that you will receive any health benefit by taking part in this research study.

Are there alternative treatments?

There may be other treatments for weight loss and there are other surgeons who will perform liposuction surgery. These treatments include prescribed food intake changes, exercise programs, and prescribed oral medications. You may also choose to get no treatment. You should talk about other treatments with

your doctor. Make sure that you understand all of your choices before you decide to take part in the study. You may also quit the study and still have these other treatments available to you.

Who is paying for this study?

The sponsor for this study is the National Institutes of Health.

Will I be paid for being in the study?

All study participants will be compensated \$500 for completing all screening and baseline testing visits, \$350 for completing the 2 month and 14 month follow-up testing, and \$50 for the 8 month test. Total compensation will amount to \$1250 if all testing is completed.

Will I have to pay for anything?

There are no costs for any of the study-related visits. As part of a special agreement made between the investigators and University of Colorado Hospital/University Physicians, Inc., a reduced-rate surgery 'package' is being offered to study participants. The costs of this 'package' are as follows: \$3510 for operating room (OR) time (including 2.5 hours in the OR and 'normal' care in the post-anesthesia recovery room) and \$3500 for the surgeon's fee (which includes suctioning of up to 4 areas of the hips and thighs). Anesthesia fees (\$850) and any additional university surcharges on the surgeon's fees will be covered by the study; therefore surgery-group subjects will be asked to pay **\$7010** at the time of surgery. Subjects will be expected to pay for any OR and anesthesia-related costs outside of the package offered. For example, if your surgery takes longer than 2.5 hours, or if you need more intense care after the surgery, you would be responsible for these costs. There are no costs for follow-up visits or hospital charges related to the overnight recovery on the CTRC.

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 do not take part in the study, your doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled.

If you chose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause your 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?

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about injury related to the research, you may call Rachael E. Van Pelt, PhD at 303-724-1917 and/or your private physician. Dr. Van Pelt should be informed about any injury you experience while you take part in this study.

If you are hurt by this research, we will give you medical care if you want it, but you will have to pay for the care that is needed.

Who do I call if I have questions?

The researcher carrying out this study is Rachael E. Van Pelt, Ph.D. You may ask any questions you have now. If you have questions later, you may call Dr. Van Pelt at (303) 724-1917. You will be given a copy of this form to keep.

While your primary source of information pertaining to participation in this study is the principal investigator (Rachael Van Pelt, PhD), a Research Subject Advocate is also available on the General Clinical Research Center at (720) 848-6662 to answer questions relating to participation in this study.

If you have questions regarding your rights as a research subject, please call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055.

Who will see my research information?

We will try to keep your medical records confidential, but it cannot be guaranteed. Records that identify you (including your medical records) and the consent form signed by you, may be looked at by the following people:

- Federal agencies that oversee human subject research
- Colorado Multiple Institutional Review Board
- The investigator and research team for this study
- The sponsor or an agent for the sponsor
- Regulatory officials from the institution where the research is being conducted, to ensure compliance with policies or monitor the safety of the study

The results of this research may be presented at meetings or published articles. However, your name will be kept private. You will be asked to sign a separate authorization form. This form will explain who will have access to your protected health information. You have the right to request access to your personal health information from the Investigator. This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Agreement to be in this study

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 know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Print Name: _____ **Signature:** _____ **Date:** _____

Consent explained by: _____ **Date:** _____

Investigator: _____ **Date:** _____

Additional Consent for Blood and Tissue for Research

The Principal Investigator (Rachael E. Van Pelt, Ph.D.) would like to keep some of the blood and tissue that is taken during the study but is not used for other tests. If you agree, the blood and tissue samples will be kept and may be used in future research to learn more about fat metabolism. The research that is done with your blood and tissue samples is not designed to specifically help you. It might help people who have obesity and other diseases related to fat metabolism in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your blood and tissue samples will not affect your care.

The choice to let Dr. Van Pelt keep the blood and tissue 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 blood and tissue samples can be kept for research, you can change your mind at any time and contact Dr. Van Pelt to let her know that you do not want her to use your blood and tissue 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. Van Pelt decides to destroy them.

In the future, people who do research with your blood and tissue samples may need to know more about your health. While Dr. Van Pelt may give the researcher reports about your health, she will not give them your name, address, phone number or any other information that will let them know who you are.

The possible benefits of research from your blood and tissue include learning more about fat metabolism and how to prevent and treat obesity. The greatest risk to you is the release of information from your health records. Dr. Van Pelt 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 blood or tissue collected and stored by Dr. Van Pelt.

Please read each sentence below and think about your choice. After reading each sentence, check "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 blood and tissue samples, you may still take part in the study.

1. I give my permissions for my blood and tissue samples to be kept by Rachael E. Van Pelt, Ph.D. for use in future research to learn more about how to prevent, detect, or treat obesity.
_____YES _____NO _____Initials

2. I give my permissions for my blood and tissue samples to be used for research about other health problems, such as causes of heart disease and diabetes.
_____YES _____NO _____Initials

3. I give my permission for one of the study investigators to contact me in the future to ask me to take part in more research.
_____YES _____NO _____Initials

I give my permission for my blood and tissue to be stored in a central tissue bank at the University of Colorado at Denver and Health Sciences Center for future use by the study investigators. I agree to take part in the study having to do with research on blood and tissue as indicated above.

Signature _____ Date _____