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 tissue may change with aging. You are being asked to be in this research study because you are a healthy man between the ages of 25-40 or 55-75 years.

Other people in this study

Up to 40 people from the local Denver Metro area will participate in the study.

What happens if I join this study?

If you join the study, you will complete the following research procedures over the course of 2 weeks. All visits will occur at the University of Colorado Hospital and Clinical Translational Research Center (CTRC).

- **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.

- **Standard blood tests** – This will involve collecting approximately 1 Tablespoon of blood and will take about 10 minutes. The blood tests measure blood cell count, electrolytes, liver and kidney function.

- **Body composition** – We will measure total body fat using a machine called a DEXA. These tests will require lying still on a table for about 10 minutes.

- **Physical Activity Questionnaire** – We will ask you to answer questions about your physical activity at work and at home. The questionnaire will take about 15 minutes and will help us understand how much activity you do daily and how it may relate to your body fat content and metabolism. We will ask you to maintain this level of activity for the remainder of the time you are in the study.
Consent and Authorization Form

Enrollment/ 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. If you agree, you will be asked to come in for testing before and after a 1 week high calorie diet.

❖ Muscle and fat Biopsies – On the day before and the day after the 1 week high calorie diet, we will take a small sample of muscle tissue from your leg and small samples of fat tissue from your leg and belly. This procedure is called a "biopsy." Before we collect the biopsy samples, we will give you some medicine (lidocaine) under the skin to numb the area. After the area is numb you may feel pressure but should not feel pain. We will then make a small cut in your skin and take the samples by pressing a hollow needle attached to a syringe into your muscle and fat tissue. When we take the needle out, it will remove a small circle of tissue called a "plug." After the muscle and fat are removed, the doctor will close the cut with a suture or steri-strip and cover it with a bandage. At this visit we will also collect a small sample of blood from your vein to measure your blood sugar and cholesterol. This study visit will take approximately 1.5 hours.

❖ 1 week high calorie diet – During the 1 week between biopsy visits you will be given a high calorie diet prepared by the CTRC metabolic kitchen. You will be given 40% more food than you normally eat. You will take home enough prepared food to last 3-4 days and then will need to return mid-week to pick up the remaining food. You will be weighed each time you pick up food. You will be asked to eat only the food provided by the dieticians and not to exercise for the 2 days before the biopsy visits.

Schedule-at-a-glance

<table>
<thead>
<tr>
<th>Test/ Visit</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation/Consent and medical history (1.5 hour)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Body composition and activity questionnaire (30 min)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fat and muscle biopsies (1.5 hours)</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood draw (10 min)</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Pick up food for high calorie diet (20 min)</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

What are the possible discomforts or risks?

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

- **Risk of DEXA scan** - As part of this study we will perform 1 DEXA scan of your whole 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 2 days.
**Risk of biopsies** - Small samples of muscle and fat will be removed from the thigh at each visit. It is possible that you could get an infection where the biopsy is taken (it happens about 1 out of 1,000 times). You may also have an allergic reaction to the numbing medicine; it is very rare (less than 1 in 10,000). You may get a small scar from the biopsy. If scars form, they are usually much smaller than the original cut and sometimes almost invisible.

**Risk of overfeeding** – In this study we will ask you to eat 40% more calories than you typically eat. The risks of overeating for one week include weight gain of up to 2 pounds, gastrointestinal discomfort, irregular bowel movements, and increased blood sugar and cholesterol levels.

**Risk of having blood taken** - In this study we will need to get a total of about 3 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.

**Loss of privacy/confidentiality** - 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 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 whether age alters how fat accumulates.

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.

**Who is paying for this study?**

The sponsor for this study is the Colorado Clinical Translational Science Institute (CCTSI).

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

You will be paid $100 for each biopsy visit in this study. This will add up to a total of $200 if you complete all of the 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 payment for participation in a study is taxable income.
Consent and Authorization Form

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.

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 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?
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.

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 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 Clinical Translational 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. A description of this clinical trial is available on http://www.ClinicalTrials.gov.

Combined Biomedical Consent and Compound HIPAA authorization
CF-151.C, Effective 7-19-13

Page 4 of 9

Initials_______
Optional Consent for Data and Specimen Banking for Future Research

Dr. Van Pelt 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 aging adipose tissue. The research that is done with your data and samples is not designed to specifically help you. It might help people who have obesity 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. Van Pelt 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 coordinator to let him or her know that you do not want Dr. Van Pelt 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. Van Pelt decides to destroy them.

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

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and samples include learning more about what causes obesity 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. 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 data or sample collection and storage by Dr. Van Pelt.

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 tissue to be stored in a central tissue bank at the University of Colorado for future use by the study investigators:
Consent and Authorization Form

1. I give my permissions for my data, blood and tissue samples to be kept by Dr. Van Pelt 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 data, blood and tissue samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).
   □ 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

Re-contact. Please indicate whether you would like to hear about future studies being conducted by our research group.

□ Yes, I am interested in being contacted to participate in future studies. ___Initials

□ No, I am not interested in being contacted to participate in future studies. ___Initials

Who will see my research information?

The University of Colorado Anschutz Medical Campus (UC-AMC) 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 – Anschutz Medical Campus
   • University of Colorado Hospital
   • Colorado State University
   • Veteran’s Administration Medical Center

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.
Consent and Authorization Form

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 UC-AMC 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.

Contact: Rachael E. Van Pelt, PhD, UC Denver, 12631 E. 17th Ave., Mail Stop B179, 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 CCTSI, 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.

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

- Name and Demographic Information (age, ethnicity, address, phone number)
- Your social security number
Consent and Authorization Form

- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Radiology Studies (DEXA scans)
- Questionnaire (physical activity)
- Tissue samples and the data with the samples
- Billing or financial information

What happens to Data, Tissue, and Blood 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, tissue, and blood given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, and blood collected from you.
- If data, tissue, and blood 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 Institutional Review Board (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.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

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

_____ I give permission for my information, from the optional procedures 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 procedures to be used and disclosed; I understand that I will not participate in any optional procedures.
Consent and Authorization Form

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 ___________________________

For non-English or non-reading volunteers:

Witness Signature: ______________________ Date: ______

Witness Print Name: ______________________

Witness of Signature ☐

Witness of consent process ☐