Clinical Investigation Consent Form IRB Rev 2021

The Rockefeller University Hospital*
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New York, New York 10065
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Title of the research study: *Identification of thermogenic silencing regulatory factors as biomarkers of metabolic health in humans*

Informed consent is the first step in deciding whether you want to join this research study. Informed consent is a process of sharing information and having your questions answered. This information will include: the purpose of the research study, what will happen in the study, and possible risks and benefits. All this information will be explained to you in detail. You should keep asking questions until you understand what the study is about and what is being asked of you. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. You can always ask additional questions at any time during the study. You have the right to withdraw from the study and you can change your mind about participating in the study at any time.

Summary of Key Information:

You are being asked to join a research study. The study will take place at The Rockefeller University Hospital. The Barrow research team from Cornell University will be collaborating on this research study. Joining a research study is voluntary. You can decide not to participate in this study. This consent form tells you about the research. The persons explaining this form to you will answer your questions. You are free to ask as many questions as you want to. You may take an unsigned copy of this form home to read again before deciding if you want to enroll. After you feel that you understand the research, you will be asked to sign this consent form if you decide to enroll. Participating in a research study is not part of your routine medical care.

The purpose of this study is: Fat is called adipose tissue. Fat plays an important role in influencing metabolic health due to its ability to store excess calories (white adipose tissue; WAT) or burn them to produce heat (brown adipose tissue, BAT). While white fat cells are located beneath the skin or around the internal organs and expand with obesity, brown fat cells live mostly in the deep neck area and have shown to turn fuel into heat when stimulated by a cold environment. This calorie burning property of activated BAT might be

* ***For use in studies not involving genetic testing described at: https://www.nysenate.gov/legislation/laws/CVR/79-L but including genome-wide genetic studies.***

a promising experimental approach to overcome the metabolic dysfunctions associated with obesity, such as insulin resistance and glucose imbalance. That approach would be to activate brown fat non-shivering thermogenesis (NST). A critical limitation with BAT as a therapeutic option, however, is that its beneficial metabolic potential is restricted in a silenced state under physiological temperature conditions for most of human life. The regulatory factors that govern this silencing process are completely unknown. The aim of this study is to unlock the metabolic benefits of human brown fat by defining the regulatory mechanisms that keep BAT in a silenced state in young healthy humans and provide data for a larger biomarker study.

The study procedures will include:

1) Fasting overnight for 12 hours (21:00 – 09:00, study to begin at 09:00 +/- 1 hour) and refraining from caffeine and excessive exercise (i.e. vigorous aerobic exercise, such as running or gym workout sufficient to increase the heart rate and perspiration) for 12 hours prior to the visit.

2) Having your anthropometrics measures for height and weight to calculate Body Mass Index (BMI), and having your accurate fat and lean body mass measured in Bod Pod (an egg-shaped device where you will sit very still inside the chamber with swimsuit and swim hat) for about a minute twice.

3) Completing food history and physical activity level questionnaires.

4) Having a blood glucose test to measure blood sugar levels using a finger prick glucometer.

5) Having a urine pregnancy test and providing information about menstrual cycles for female participants.

6) Wearing a cooling vest (which will feel cold, 60-64F) for three (3) consecutive hours followed with another three (3) consecutive hours for re-warming.

7) Having a total of six (6) blood collections. One (1) blood draw of 35 mL (approximately 7 teaspoons) for eligibility test and baseline measurement, and another five (5) blood draws each of 16 mL (approximately 2 teaspoons) over a span of 6.5 hours before and after both cooling and re-warming process. The total volume of blood sampling (80 mL or about 5.5 tablespoons) is in accordance with the American Red Cross safety guidelines.

8) (Optional) having two (2) skin/fat punch biopsies of 6 mm in diameter (about ¼ inch, the size of a pencil eraser) obtained after both cold and warm environmental exposure.

How long will you be in the study: If you join the research study, you will take part for about 10 hours. The study will involve two (2) study visits and one (1) remote pre-visit.

Pre-visit will take over zoom for less than 30 minutes. The first visit will last approximately 2-3 hours, and the second visit will last about 6.5 hours. The research study as a whole will last about 2 years.

Number of participants involved: 120.

Before you decide whether to participate in the study, it is important for you to know the main risks of the study:

1) Wearing the cooling vest is uncomfortable due to feeling cold. There is a rare risk of hypothermia (very low body temperature) while wearing the cooling vest.

2) The risk associated with the Bod Pod experience is the possibility of feeling claustrophobic.

3) The risks associated with having your blood drawn include discomfort, pain, bleeding, bruising, infection at the needle site, and fainting or feeling lightheaded.

4) The risks associated with skin/fat punch biopsy (optional) include potential scars. Scars may continue to change for many years after the sutures are removed. In addition, everyone heals differently, and it is possible that the scars may be red for some time, or become raised, darker, or lighter than the surrounding skin.

These are described in greater detail below in Section III on Page 10.

The possible benefits of participating in this study are: There is no direct benefit from your participation in this study. However, the information you provide may help others in the future.

Researcher's contact number:

Primary contact:

Joeva Barrow, Ph.D., R.D.; Phone: 352-575-7051, Email: jb2254@cornell.edu

Secondary contact:

Paul Cohen, M.D., Ph.D.; Phone: 212-327-7918, Email: pcohen@rockefeller.edu

Muying Li, M.S., R.D.; Phone: 917-593-9655, Email: ml2363@cornell.edu

I. What this research study is about, and the reason for doing this research.

All humans have fat and recently, scientists have been studying the role of fat in our health. Fat plays a major role in influencing our metabolic health such as developing diabetes and heart disease. There are different types of fat. For example, there is white fat, also known as white adipose tissue (WAT) which stores excess calories. There is also brown fat, also known as (brown adipose tissue (BAT), which burns calories. While white fat cells are located beneath the skin or around the internal organs and expand with obesity, brown fat cells live mostly in the deep neck area and have emerged to turn fuel into heat when activated by a cold environment. This calorie burning property of activated BAT suggests a promising experimental approach to overcome the metabolic dysfunctions associated with obesity, such as insulin resistance and glucose imbalance, is to activate brown fat non-shivering thermogenesis (NST). A critical limitation with BAT as a therapeutic option, however, is that its beneficial metabolic potential is restricted in a silenced state under physiological temperature conditions for most of human life. The regulatory factors that govern this silencing process are completely unknown. The aim of this study is to unlock the metabolic benefits of human brown fat by defining the regulatory mechanisms that keep BAT in a silenced state in young healthy humans and provide data for a larger biomarker study. The intent is to cool and rewarm your body to identify blood proteins induced by a cool and warm environment. Since current methods of BAT detection in humans rely on deep neck biopsies and/or costly PET/CT scans, identification of blood factors that show BAT activity would offer a cost-effective, non-invasive alternative in humans.

We are asking you to take part in this research study because you are a healthy volunteer. Cornell University will be collaborating with us on this research study.

II. What is going to happen in this research study?

Test and Procedures Involved with this Study

Consent Process and Remote Pre-Visit

In a less than 30-minute pre-visit over zoom, you will review a one-page infographic containing the study design and go through the informed consent process. Informed consent is a process to help you understand the purpose of the research study, what will happen in the study, possible risks and benefits, and your right to withdraw from the study at any time. All this information will be explained to you in detail. You should ask any questions you have until you feel that you understand what is asked of you to participate. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. Even after the study has started, you may at any time ask more questions, or decide to withdraw from the study.

During this meeting, your basic information will be asked (your date of birth, sex, pregnancy, weight history, metabolic disease, etc.). If you are eligible based on the study's inclusion and exclusion criteria, you will be asked to provide electronic informed consent by signing the eConsent via REDCap according to the established eConsent Standard

Operating Procedure (SOP) and will be enrolled in the study. A suitable date for in-person on-site Visit #1 will be established at the end of the meeting.

In this part, we explain the meaning of words that we are going to use to describe this study:

> "Substances drawn from your body" refer to liquids such as blood or urine. It can also mean tissues such as skin, cells, and DNA. Cells make up all parts of your body. DNA is inside all the cells of your body and carries your genetic or inherited information. When we draw blood, take tissue, or take other substances from your body, we are taking a "sample."

There will be two (2) in-person on-site study visits at the Rockefeller University Hospital (RUH). You can decide to terminate the procedures at any point during the visit.

VISIT #1

VISIT #1 will take approximately 2-3 hours. A breakfast meal will be provided by the RUH Bionutrition department's metabolic kitchen.

You will be instructed to have a hearty meal of choice the evening before Visit #1 and then fast overnight for 12 hours prior to the experiment (21:00 – 09:00, study will commence at 09:00 +/- 1 hour). You will need to refrain from caffeinated beverages and excessive exercise (i.e., vigorous aerobic exercise, such as running or gym workout sufficient to increase the heart rate and perspiration) for 12 hours prior to the visit as well.

During this meeting, your anthropometrics (weight and height) will be measured to calculate Body Mass Index (BMI). Your body fat and muscle composition will also be assessed via Bod Pod following Rockefeller's standard operating procedures. Clinical staff will then obtain blood for basic clinical labs. If you are a female of childbearing potential, you will also provide urine to determine if you are pregnant and be asked to provide information about your menstrual cycle. If you are pregnant, you will not be eligible to participate in the study.

> **Bod Pod:** This test measures total body weight, and the percentage of fat and lean mass in the body. It is performed after an overnight fast. During the test, you will be required to wear a swimsuit (or other light, form-fitting clothing, such as a sports bra or tank top and bike shorts or leggings; nothing that has an underwire or metal) and a swim cap. You will have to bring your own swimsuit or any other clothing for the Bod Pod mentioned above, other than a swim cap, which we will provide. You must remove all jewelry, watches, eyeglasses, body piercings and other accessories. You will be seated in a pod-like chamber that will be enclosed but has a window. Your overall body composition will be calculated. The test is performed twice, with the door closed for ~ 1 minute, each time and the total procedure takes 10-15 minutes.

During any activity designed for Body Composition testing, the measurements can be interrupted, if necessary, by pressing on the green "Cancel Test" button on the test chamber seat. When this button is pressed, the test chamber door electromagnets are de-energized allowing the door to be opened and the activity being conducted is terminated. The research participant is told where the green "Cancel Test" button is located should they want to stop the test for any reason. The Bod Pod is located in the Out-Patient Department, in a private room with an emergency call bell. The Nursing Staff station is a few yards away from this room's location.

Blood Collection: After the Bod Pod, you will have your blood drawn while you are wearing your regular clothes. 35ml of blood (approximately 7 teaspoons) will be drawn from a vein in your arm or hand. Your blood will be studied for insulin, HbA1c, triglycerides, thyroid hormone (TSH) for research purposes. Your blood glucose levels will be determined with a fingerstick using a glucometer to ensure normal glucose levels.

Following these assessments, a breakfast meal prepared by the RUH Bionutrition department's metabolic kitchen will be provided to you. You will then engage in comprehensive nutrition assessments which consist of a diet history and a physical activity level questionnaire. You will first fill out the Diet History Questionnaire III (DHQ III) by the National Cancer Institute to obtain diet quality and patterns information under the supervision of research staff from the Barrow research team. Research staff will then conduct a structured interview of a 4-question International Physical Activity Questionnaire (IPAQ) to evaluate your physical activity level. The nutrition assessments allow researchers to calculate your estimated energy requirements (EER) and nutrition requirements using the gold standard EER equations developed by the National Academies of Sciences, Engineering, and Medicine Dietary Reference Intakes for Energy (DRI) 2023 for individuals.

A suitable date for Visit #2 (experiment date) will be established at the end of the meeting.

VISIT #2

VISIT #2 will start at 9am and take approximately 6.5-7 hours. A tailored chilled complete liquid nutrition meal replacement beverage (Katefarms) will be provided by the bionutritionist from the RUH Bionutrition department.

You will be instructed to have a hearty meal of choice the evening before Visit #2 and then fast overnight for 12 hours prior to the experiment (21:00 – 09:00, study will commence at 09:00 +/- 1 hour). You will need to refrain from caffeinated beverages and excessive exercise (i.e., vigorous aerobic exercise, such as running or gym workout sufficient to increase the heart rate and perspiration) for 12 hours prior to the visit as well.

This visit includes a customized cold environmental exposure for consecutive three (3) hours, and subsequently a re-warming/thermoneutral exposure period for consecutive three (3) hours. There will be five (5) blood collections of 16 mL (approximately 2 teaspoons) each for a total of 80 mL (approximately 5.5 tablespoons) over a span of 6.5 hours and two (2) optional skin/fat punch biopsies obtained after cold and warm environmental exposure that will be cryopreserved for transcriptomic analysis. The total volume of blood sampling is in accordance with the American Red Cross safety guidelines.

Prior to the Cooling Process: You will be instructed to de-robe in private quarters and change into hospital gowns and socks, which will be provided. The only additional clothing you will wear is your underwear.

> **Baseline Blood Collection:** You will have your first baseline fasting blood draw of 16mL (approximately 2 teaspoons).
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> **Breakfast:** You will be provided an individualized chilled complete liquid nutrition meal replacement beverage (Katefarms) as "breakfast." The amount of formula meets a third of your dietary reference intakes (DRI) for energy based on your EER that was calculated in Visit #1. This nutrition beverage is USDA Organic, Non-GMO, plant-based, vegan, and does not contain milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, or soybeans.
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> **Second Blood Collection:** 30 minutes after finishing eating, you will have your second blood draw of 16mL (approximately 2 teaspoons).

The Cold Exposure (three (3) hours): We will help you put on a clean cold vest (see the picture below) with adjustable straps attached to a small 'cooler' reservoir to circulate cold water between the vest and the cooler). You may not wear any clothing over the vest.

Cooling Process: The temperature of the vest will be lowered until the coldest tolerable temperature is reached. This will be the coldest temperature before shivering occurs. The starting infusion temperature will be set to 16°C/60.8°F. Both researchers and hospital staff will monitor for signs of shivering. When shivering occurs, the temperature setpoint on the cold vest will be raised by increments of 2°C/35.6°F until shivering subsides which will be the defined cooling temperature for that individual throughout the study period. If shivering does not occur within a 10-minute period, then the temperature will be lowered by increments of 2°C/35.6°F until shivering begins, at which the setpoint will be increased by +2°C/35.6°F. The cold vest will then be kept on for three (3) hours with a temperature set to the coldest tolerable temperature.

Hospital staff will monitor your body temperature by a thermometer reading taken from your ear and ask your comfort level every 30 minutes.

You will remain seated during the cooling period. You will not be allowed to eat during the experiment but will be provided with cold water. You will be allowed to read/do computer work during the study, if you have a laptop or tablet it will be placed on a desk in front of you (not on your lap, to avoid heat transmission). You will be free to use the restroom as needed. The vest will be removed to allow you to use the restroom and then placed back on once you return for the remainder of the cold-exposure phase.

Third Blood Collection: At the end of cold exposure, you will have another blood draw of 16mL (approximately 2 teaspoons).

Re-warming Process: After 3-hour cold exposure, the vest will be removed and you will then be warmed with a blanket. You will be moved to an adjacent warm room maintained

at 30°C/86°F. You will engage in reading and/or digital entertainment for the remainder of the 3-hour warm exposure period.

Fourth Blood Collection: Blood draw of 16 mL (approximately 2 teaspoons) will occur 45 minutes after the transition to warm temperatures. This will be a critical sampling period as we hypothesize that the NST program will be shutting down in response to the warm temperatures and therefore sampling at this time will maximize the potential of identifying regulatory factors that govern the acute phase of NST silencing.
Lunch: Following blood collection, the bionutritionist will provide you with a second chilled liquid nutrition meal replacement beverage meeting a third of your DRI for energy at ~1:15pm to represent the "lunch" meal. This will ensure that you will continue to remain in the fed state throughout the study.

Last (Fifth) Blood Collection: At the end of 3-hour re-warming process, you will have the last blood draw of 16mL (approximately 2 teaspoons).

Skin/Fat Punch Biopsy (Optional): If you agree to donate skin/fat punch biopsies, at the end of both the cold and warm exposure periods, Jeanne Walker, DNP, ANP-BC at the Rockefeller University who is experienced in performing these procedures will perform a skin/fat punch biopsy according to established standard operating procedures. Briefly, the skin/fat punch biopsy is a minor surgical procedure where a small piece of skin and some underlying fat tissue is removed from the participants lower abdomen after it has been numbed with local anesthesia (1-2% xylocaine). Two biopsies of 6 mm in diameter (about ¼ inch, the size of a pencil eraser) will be obtained. The skin will be closed with absorbable sutures.

Some parts of this study are experimental. Here, the word "experimental" means that the test or the treatment is "not part of the usual routine care of patients". It is the wearing of a cooling vest.

Laboratory testing conducted on your blood or tissues during the research study will fall into two general categories: 1) New York State-approved tests, and 2) experimental tests that have not been certified by New York State.

> *A New York State-approved test* is a standard laboratory test performed by a New York State-approved laboratory during the research study. We will tell your doctor and/or you about any test results that may affect your health. We will give you a copy of all your laboratory results that were performed by a New York State-approved laboratory.
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> *Experimental tests* have not been approved by New York State for diagnosis or treatment. By law, we cannot tell you or your doctor the results of experimental tests; however, if we find anything from experimental tests that might be important

for your health, we may suggest that you have additional tests performed by a New York State-approved laboratory.

We will tell you or your doctor about any tests related to the research protocol that are performed by a New York State-approved laboratory, if the results may affect your health or safety.

By law, we cannot tell you or your doctor the results of experimental tests, that is, tests that have not been approved by New York State for diagnosis or treatment; however, if we find anything from experimental tests that might be important for your health, we may suggest that you have additional tests performed by a New York State-approved laboratory.

In this study, you will not receive routine care for any medical conditions related to this protocol. In this study, you will not receive routine care for any other medical conditions you may have.
Your medical information and test results will be written in your hospital chart. The researchers of the study may also keep separate records with information about you and your study tests.

Sometimes we will need to look at your earlier medical records. We will ask you to sign a medical release form that will give us permission to obtain your health information from another hospital, doctor, or clinic where you have been treated previously.

III. What are the risks of taking part in this research study?

There may be some risks and discomforts in taking part in this study. These are the ones we know about now:

The potential risk associated with fasting for 12 hours is that you may feel hungry and uncomfortable.

The risk associated with Bod Pod testing is the possibility of feeling claustrophobic (sense of being suffocated in a small, enclosed area) during the procedure. If this happens, the test can be stopped by participants pressing on the green "Cancel Test" button on the test chamber seat. When this button is pressed, the test chamber door electromagnets are de-energized allowing the door to be opened and the activity being conducted is terminated. The research participant is told where the green "Cancel Test" button is located should they want to stop the test for any reason. The Bod Pod is located in the Out-Patient Department, in a private room with an emergency call bell.

The risk associated with wearing the cooling vest is feeling cold. There is a rare risk of hypothermia (extremely cold body temperature) while wearing the cooling vest. During the cold exposure, researchers and hospital staff will continuously monitor signs of shivering and adjust the vest temperature accordingly. Hospital staff will

also check your body temperature and level of comfort every 30 minutes. If hypothermia happens, the procedure will be stopped immediately. The vest will be taken off from you and a blanket and warm drinks and snacks will be provided.

The risks associated with having your blood drawn include discomfort, pain, bleeding, bruising, infection at the needle site, and fainting or feeling lightheaded.

A skin/fat punch biopsy produces a small scar. Other potential side effects include pain, bleeding, or bruising at the site. Rarely a patient may develop a superficial skin infection. In people prone to keloid formation, a biopsy may heal with a keloid. Occasionally people may faint or become lightheaded during the procedure. These skin/fat punch biopsy sites heal in a variety of ways. The final appearance will depend in part on the area of the body biopsied, the reason for the biopsy, and the underlying skin appearance before the biopsy. Scars may continue to change for many years after the sutures are removed. In addition, everyone heals differently, and it is possible that the scars may be red for some time, or become raised, darker, or lighter than the surrounding skin. You will most likely have a permanent scar of some kind and looking at your prior scars may give the best prediction of your long-term healing.

Privacy Risks: There is the risk that there could be computer security breaches that could reveal your identity. There may be the risk that data about you may become public and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

There may be other risks and discomforts that we do not know about now, but we will tell you if any new information is discovered that might affect your decision to participate or remain in the study.

IV. What are the alternatives to participating in this research study?

You have the option not to participate in this study.

V. What are the benefits of taking part in this research study?

There are no direct benefits to you from taking part in this study, however, the information you provide may help others in the future.

VI. Who will be able to see the information learned about you in this research study?

We will keep your personal information private and will do our best to keep this information confidential. We will listen to what you say about what we may do with this information, and we will follow the law. For example, by New York State law, hospitals must inform the New York State Department of Health if we find that you have a

reportable communicable disease, such as a viral disease like COVID-19, or a sexually transmittable disease, like chlamydia, hepatitis, gonorrhea, syphilis, and HIV-1. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

During this study, only the researchers will know that your samples came from you, because your stored samples will be identified only by a special code instead of your name. As a result, others who study your samples will not know that they came from you and will not be able to figure out that they came from you. For example, the data received by sponsors would be identified only by a code. However, auditors and regulators from government agencies that oversee research, and people at the Rockefeller University Hospital and at Rockefeller University may see your information in the course of their duties. Staff that view data with personal identifiers have received privacy training and are required to adhere to privacy and confidentiality laws and policies.

Your privacy is very important to us, and we will use many safety measures to protect your privacy. However, despite all the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Therefore, it is possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. We may deposit your genetic data to databases/repositories available to others for research. While neither the public nor the controlled-access databases/repositories developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in a database/repository back to you. For example, someone could compare information in one database/repository with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease. If concerns over non-paternity or non-maternity arise, they will not be divulged under any circumstances.

If the researchers publish the results of this study, they will not mention your name or other information that could identify you.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Genetic Information Nondiscrimination Act

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal in the United States of America for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information is available in the Rockefeller University Hospital Outpatient or Inpatient Information Handbook.

There may also be privacy risks that we have not foreseen.

VII. What are the payment arrangements?

There is no cost to you for being in this research study.

You will be compensated $300 upon completion of the study. If you decide to skip or stop a procedure, you will be compensated for the portion of the study you completed. An extra total of $100 will be compensated for completing two skin/fat punch biopsies.

Payment will be made to participants who are eligible for and want to receive payment and who fill out a brief form with tax identification information from The Rockefeller University Finance Office. Your information will remain confidential unless required to be

disclosed by federal, state, or local laws. If you do not want to complete the form, you can still participate in the study but will not be eligible for compensation.

If research using your samples helps develop a drug or another product that is sold to the public, the drug company, the University, and the researcher may share in some of the profits. For example, a cell line from your samples could be used to make a product for sale. There are no plans to pay you any money resulting from such discoveries. However, by signing and dating this form, you do not give up any rights you may have.

VIII. What happens if you don't want to stay in this study or your participation is ended?

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty, and no one will hold this against you. You may change your mind and stop taking part in this study at any time, and this will not be held against you. Information about you up to the time you stop participating in the study may remain a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join the study now but later want to stop, you should let the researcher know via the contact methods described above in the end of "Summary of Key Information" on Page 3.

The researchers may stop you from continuing to take part in this study, even if you do not choose to stop being in it.

IX. Whom do you call if a medical problem results from this research study?

If you believe that this study has led to a medical problem, you should call the researcher listed below right away. The researcher will help you get appropriate, available medical care.

Name: Paul Cohen, M.D., Ph.D.
Phone: 212-327-7918
Email: pcohen@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in this study at The Rockefeller University Hospital. However, you do not give up any rights you may have to seek compensation by signing and dating this consent form.

X. Whom do you contact if you have questions about the research study?

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later, contact the following researcher:

Primary contact:

Name: Joeva Barrow, Ph.D., R.D.
Phone: 352-575-7051
Email: jb2254@cornell.edu

Secondary contact:

Name: Paul Cohen, M.D., Ph.D.
Phone: 212-327-7918
Email: pcohen@rockefeller.edu

Name: Muying Li, M.S., R.D.
Phone: 917-593-9655
Email: ml2363@cornell.edu

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-8408.

XI. Consent to the use, storage and sharing of your samples and other data for separate research studies

The scientific value of your samples and the information obtained from them, and the other data collected in this study is greatly increased if we can share them with other scientists at universities, sponsors, and pharmaceutical or technological companies worldwide. If you allow this, your samples, sample information, and other data collected in this study will be used for biomedical research including genetic analyses. You will not be provided details of any specific research studies or their purpose. In general, identifiers will be removed from the identifiable private information or identifiable biospecimens. Afterwards, the biospecimens, biospecimens information, and other data collected in this study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. May we:

- store, use, and share for many years your biospecimens, biospecimen information including genotype and phenotype data*, and other data collected in this study with other investigators at Rockefeller and elsewhere, possibly worldwide, and including sponsors, pharmaceutical and technology companies, sample and/or data banks/repositories for separate studies? Your biospecimens will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so the chance of linking samples to you is reduced. Other data, including related to

your biospecimens, but that does not identify you, may accompany the specimens; and

- put anonymous data collected from the study and information from the analyses in a completely public database, available to anyone on the Internet; and
- put your coded genotype and phenotype* medical data information and other data collected from the study and information from more detailed analyses of your coded samples into a National Institutes of Health (NIH) controlled-access database/repository? The information in this database/repository will be available only to qualified researchers from academic institutions and commercial organizations, both domestic and foreign who have received approval from an NIH Data Access Committee.

* The genetic information obtained from your DNA is called genotype. The information about your disease condition and the physiology of your cells is called phenotype.

Yes _____ No _____

If you say "No" you may still participate in this study.

At any time in the future, you may withdraw your consent to use any samples and other data that have not already been used in research or shared. If you withdraw your consent, the remaining unused samples will be destroyed, unless the samples cannot be identified as having come from you. Data generated using your samples will continue to be used.

XII. May we have permission to contact you about future studies?

May we contact you by phone or email to find out if you are interested in hearing about new research studies? (We will not share your contact information for any other purpose). Contact would be made by the staff of the Rockefeller Clinical Research Support Office for recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will no longer attempt to contact you.

Would you like us to contact you about future research studies?

Yes _____ No _____

If you say "no" to this question, this will not affect your participation in this study.

AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED

I have read this consent form, and my questions have been answered.

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and afterwards.

I hereby voluntarily consent to take part in this research study.

STANDARD PARTICIPANT SIGNATURE BLOCK

Name of the Study Participant (Print) _____

_____ _____

Signature of Study Participant **Date (To Be Filled in by Study Participant)**

ALTERNATE SIGNATURE BLOCK

Participant requires assistance by a translator

Translation Services Provided by (check only one box below):

☐ **Pacific Interpreters**

_____	_____
Language	**Translator Identification Number**

Name of the Study Participant: _____
(Print Name)

Witness to telephone translation:_____
(Print Name)

_____	_____
Signature of Witness	**Date**

☐ **Other Translator:**

_____	_____
Name of Translator	**Date**

Witness to oral presentation: _____
(Print Name)

_____	_____
Signature of Witness	**Date**

Signature of the Person Conducting the Informed Consent Discussion

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

Name of Person Discussing Consent _____
(Print)

_____	_____
Signature of Person Discussing Consent	**Date (To Be Filled in by Person Discussing Consent)**