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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 01/02/2020

Protocol Number: 2009P000101

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
06/09/2020
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: The Physiology of Human Brown Adipose Tissue
PRINCIPAL INVESTIGATOR Mary-Elizabeth Patti, MD
PROTOCOL NUMBER: 2009P-000101

Aim A

INTRODUCTION:

You are invited to take part in a research study about two types of fat tissue in the body – brown fat and white fat. Brown fat is a type of fat, found in both children and adults, which can produce heat and regulate the body's metabolism and energy use. White fat is the more common type of fat which is used to store extra calories. Understanding more about differences between brown and white fat may allow us to develop new approaches to improve the body's metabolism. .

You are being asked to take part in this study because you are already undergoing surgery, either for treatment of your spine or to have something removed such as your thyroid, parathyroid, or adrenal glands. Research studies include only people who choose to take part. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study.

- Your participation is voluntary;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with your doctor or with Beth Israel Deaconess Medical Center.

Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

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DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Mary-Elizabeth Patti and is funded by the National Institutes of Health (NIH) and a private foundation (the Chan-Zuckerberg Initiative). The funding agencies in this study are paying Beth Israel Deaconess Medical Center to perform this research. BIDMC and Dr. Mary-Elizabeth Patti, Dr. Andrew White, Dr. Peter Mowschenson, Dr. Gerald Kolodny, Dr. Yu-Hua Tseng, and Dr. Per-Olof Hasselgren have no additional interests in this research project.

WHY THIS STUDY IS BEING DONE

Brown fat is a type of fat found normally in human children, and its purpose is to generate heat. In small animals, brown fat also increases weight loss and improves the body's sensitivity to insulin, the hormone that lowers blood sugars. For many years, it was thought that brown fat did not exist in adult humans. However, recent medical studies have shown that brown fat can be found in a significant percentage of adults, and there is a connection between the amount of brown fat in people and their degree of obesity. In mice, increases in brown fat can increase the amount of calories burned off.

What we don't know yet is whether human fat cells can be stimulated to increase the amount of calories burned. Therefore, we designed this study to learn more about brown fat cells, and to compare them with white fat cells from the same person. We want to collect fat cells to see what they look like at high magnification, and what genes and proteins they make. Some of the cells will be studied immediately, and some will be grown and matured in the laboratory to make brown and white fat cells.

WHO WILL PARTICIPATE IN THE STUDY

Up to 100 people will take part in this study at Beth Israel Deaconess Medical Center.

WHAT WILL HAPPEN DURING THE STUDY

You are already planning to undergo a surgical or radiologically-guided procedure to do one of the following: (a) remove a tissue such as your thyroid, parathyroid, or adrenal glands; (b) have an operation on your spinal column; (c) posterolateral lumbar spinal fusion surgery; or (d) image-guided biopsy of the liver, kidney, adrenal, or other organ. During your procedure, your doctor will remove 3-6 grams (which is roughly the size of a couple of lima beans, or 0.1-0.2 ounces) of fat tissue that will be collected and processed in the laboratory to be studied by at high magnification (high-powered light and electron microscopy) and analyzed for protein function and to identify genes which are turned on or off. Some of the cells will be grown in the laboratory and used to make cell lines which can be used repeatedly for experiments to test different ways to make more brown fat or to improve its function.

Information about which genes and proteins are made in brown or white fat will be shared with other scientists. This information will not include any information which could identify you, such as name, date of birth, medical record information, or other identifiers.

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If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

Blood sample: A blood sample will be collected during a preoperative office visit. This will be used to measure markers of metabolism: leptin, adiponectin, insulin, glucose, and hemoglobin A1c, and to collect blood for DNA analysis. The total volume required will be 30 cc (about 2 tablespoon of blood).

Fat Biopsy – The tissue collection portion of this study is performed during your scheduled procedure at the Beth Israel Deaconess Medical Center. Routine preoperative procedures will be followed, including local anesthesia (numbing a particular region of the body) or general anesthesia (being put to sleep). These procedures can be explained in more detail by your surgeon**.** Once your surgeon is in the process of the spinal surgery or removing your thyroid, parathyroid, or adrenal gland, he will remove up to 5 pieces of fat tissue measuring in total of about 3-6 grams (0.1-0.2 ounces). Your surgeon will otherwise proceed as usual with your surgery. After surgery, he will provide the standard medical care.

Blood Test Results: The study team will review your blood testing results for glucose and hemoglobin A1c. If you agree, the team would like to notify you of clinically significant results by mail or phone, and will also notify your primary care provider as well.

☐ I authorize the study team to provide me a letter of my clinically significant results of the study. _____ Participant's Initials

☐ I **do not** authorize the study team to provide me a letter of my clinically significant results of the study. ____ Participant's Initials

☐ I authorize the study team to contact my primary care physician, as needed. _____ Participant's Initials

☐ I **do not** authorize the study team to contact my primary care physician, as needed. _____ Participant's Initials

Genetic Research

As part of this research, we will collect and store information about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions.

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Genomic information relates to the structure and function of all of the genetic material in the body.

Fat Biopsy: The fat biopsy will be used to identify how genes are turned on and off, and how this process is different in fat from different areas of the body and from different people. This information will be put into databases such as the Human Cell Atlas and used for future research. Your name and other information that could identify you will not be included in the database. We will not know what types of health-related research will be done with the data that are sent to the public database. We do not think that there will be further risks to your privacy and confidentiality by sharing your anonymous genetic and health information with this database. However, we cannot predict how the information about how genes are turned on or off will be used in the future, or whether such information (considered anonymous now) will be identifiable at a later date through other scientific advances.

Blood Sample: We may perform a whole genome or whole exome analysis on your blood sample. Some research involves just studying a few genes that are known or suspected to be linked to a disease or condition. In whole genome or whole exome analysis, all or most of your genes are tested and used by researchers to try to find causes of obesity, diabetes, other metabolic diseases as well as how your brown adipose tissue functions. Even if whole genome or whole exome is performed, the researchers may not study every single gene that you have in order to conduct this research and may not be aware that you have genes that could predict your risk of having or developing a certain disease or condition. It is also possible that this type of testing will discover a gene that we do not yet have information about that may put you or a relative at risk for a genetic disorder in the future, but the researchers will not know that during the course of the study.

The US National Institutes of Health (NIH) and other central repositories have developed special databases to collect the results and analyze data from genetic studies. The aim of collecting this information in central databases is to allow researchers to look for genetic connections for a range of topics in the future. The information may be used to learn if certain genes:

- may increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease, or mental illness) or a condition (such as high blood pressure or obesity),
- may affect the progress of a certain disease or condition, or
- may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

As part of this study, we will be collecting information about your health and your individual genes. We will use this information for our study objectives. In addition, this information, along with information about other people in this study, will be put in databases including the U.S. National Institutes of Health (NIH) genomic database called dbGAP, the NIH Genome Wide Association Study (GWAS) and the Human Cell Atlas and used for future research.

Anonymous genetic and health information from the analyses of your samples may be put in public

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access databases including the NIH dbGAP, NIH GWAS and the Human Cell Atlas. This information will be used for future research. Your name and other information that could identify you will not be included in the database. We will not know what types of health-related research will be done with the data that are sent to the public database. We do not think that there will be further risks to your privacy and confidentiality by sharing your anonymous genetic and health information with this database. However, we cannot predict how genetic information will be used in the future, or whether such information (considered anonymous now) will be identifiable at a later date through other scientific advances.

There is a risk that someone in the future could link your genetic or medical information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance; however there are laws against this kind of misuse. We believe the chance these things will happen is very small, but we cannot guarantee that your identity will never become known. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.

POSSIBLE RISKS, SIDE EFFECTS, AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Blood sample: The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

The maximum volume of blood taken is 30 cc, or about 2 tablespoon of blood. This should not pose any health risk to you.

If the blood testing shows that you have diabetes or prediabetes, a member of the study team will contact you, and will share this information with both you and your primary care physician, if you have indicated your consent above.

Fat Biopsy: You should not experience pain during the fat biopsy done during your surgery because you will be either sedated or asleep (under general anesthesia). Small amounts of bleeding from the specific site of the biopsy might occur and would be controlled by your surgeon. There is no measurable increase in risk of infection from the biopsy itself since you are already being exposed to the risk of infection by your medically needed surgery. The biopsy procedure may increase the length of the operation by two-three minutes. You should not experience any long-term side effects from the biopsy procedure.

Other Risks: Volunteers may be inconvenienced by the time commitment required of the study. There

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are risks of breach of confidentiality, however all persons conducting clinical research will have completed education programs on the ethical conduct of clinical research and on patient privacy protection. There may be other risks from participating in this study that are currently unknown or unforeseen.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

POSSIBLE BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you may choose not to enroll in the study.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor or with Beth Israel Deaconess Medical Center. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study

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procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for the blood tests or laboratory studies that we will do after collection of the fat tissue. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU:

You will receive $25 as financial compensation for your time.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Payment will be provided at the completion of the study, or, if you do not complete the entire study, you will be paid for the parts you completed. Questions about your own tax status should be referred to your personal tax advisor.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section “Who to Call if You Have Questions” in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan for other reimbursement will be provided for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

CONFIDENTIALITY

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory

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agencies, accreditation agencies, the Committee on Clinical Investigations and the Human Subjects Protection Office of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

CERTIFICATE OF CONFIDENTIALITY

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information or specimens that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing your information or specimens if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or for use in other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. By signing this form, you are giving your consent to the disclosure of your information or specimens for any purpose you have agreed to in this informed document and for any purpose permitted without additional authorization in the BIDMC Notice of Privacy Practices. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information or specimens, then the researchers are permitted, but not necessarily required, to disclose that information.

USE OF YOUR TISSUE AND DATA FOR COMMERCIAL DEVELOPMENT

As part of this research program, samples of your tissue, cell lines made from your tissue, and information about your medical history may be provided to other researchers and/or outside collaborators without identifying you by name. They may use your tissue and information in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from any such work that may be performed. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your tissue may be used for commercial purposes. You also understand and agree that tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. Beth Israel Medical Deaconess Medical Center has no program to compensate you in the event product testing or commercial development takes place.

Information about genes turned on or off in your tissue will be shared with the scientific community via online databases. This information will not include anything which could identify you. This information could be used by other scientists to develop new knowledge. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that this information may be used for additional scientific and/or commercial purposes.

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AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting and sharing information about you with others. Please review this section carefully as it contains information about the federal privacy rules and the use of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists such as medical records and laboratory tests as well as any new information generated as part of this study through the tests and procedures] we may ask you to undergo. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with investigators listed on this consent form as well as the supporting research team [i.e. research assistants, statisticians, data managers, laboratory personnel, administrative assistants]. Your Protected Health Information may also be shared with the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center as it is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The other hospitals and medical centers taking part in this study [Joslin Diabetes Center] and research collaborators at those institutions.
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], and the Office for Human Research Protections [OHRP]
- Hospital and Clinical Research Accrediting Agencies
- LabCorp
- Harvard Catalyst Central Lab

Those who receive your Protected Health Information may make further disclosures to others. If they do, your information may no longer be covered by the federal privacy regulations.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the

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research as described in this Informed Consent Document. We also shall use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Mary-Elizabeth Patti, MD, Joslin Diabetes Center, One Joslin Place, Boston, MA. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter.

REFUSAL TO SIGN

If you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

NOTICE OF PRIVACY PRACTICES

In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

WHOM TO CALL IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions about this research or experience any problems, you should contact Mary-Elizabeth Patti, MD at (617) 309-1966.

If you have questions regarding your rights as a research subject or would like to obtain information or to offer input about the research study, you may contact the Human Subjects Protection Office at [617] 975-8500. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____