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

Administrator: Lily Moy (TMO)

Consent Approval Date: 10/24/2016

Protocol Number: 2014P000335

Study Approval Expiration Date: 10/10/2017

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
10/10/2017
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: **Mechanisms of weight loss with SGLT2 inhibition**
PRINCIPAL INVESTIGATOR: **Jody Dushay, MD**
PROTOCOL NUMBER: 2014P-000335

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- 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 any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

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. 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.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Jody Dushay and is funded by Janssen Scientific Affairs, LLC. The funding agency in this study, Janssen Scientific Affairs, LLC is paying Beth Israel Deaconess Medical Center to perform this research and is providing study treatment. Dr. Dushay has additional interests in this research project or in the funding agency as follows: Dr. Dushay has served as a paid consultant on a scientific advisory panel for Janssen Scientific Affairs, LLC.

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A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Jody Dushay at [617] 667-1996.

PURPOSE

The purpose of this study is to investigate the effect of canagliflozin, a medication approved by the FDA for the treatment of type 2 diabetes, on body weight and metabolism in people with type 2 diabetes who are overweight or obese. Canagliflozin lowers glucose levels in the blood by making the kidney excrete, rather than absorb, glucose. Canagliflozin is also often associated with weight loss. It is not known how canagliflozin causes weight loss or affects metabolism in people with type 2 diabetes.

STUDY PARTICIPANTS

You have been asked to be in the study because you have type 2 diabetes and you are overweight or obese. Approximately 60 people will take part in this study at Beth Israel Deaconess Medical Center. This study is not being conducted at any other institutions. All study visits will take place in the Harvard Catalyst Clinical Research Center at the Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

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:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include: A medical history including history of your diabetes care and blood sugar control, your body weight history, and your current medications; a physical exam including height, weight, blood pressure and heart rate; a blood test that will measure your white and red blood cell counts, electrolytes, kidney function, liver function, thyroid function, cholesterol levels, blood sugar control, and markers of inflammation and metabolism. We will also collect a urine sample for measurement of glucose and protein. If you are a woman of childbearing age, you will be required to have a urine pregnancy test unless you have not had a menstrual period in more than 2 years or you have had a surgical procedure which makes it impossible for you to become pregnant. If the pregnancy test is positive, you will not be allowed to participate in this study. You will come to the screening visit after an overnight fast.

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2. Randomization Procedures:

   You will be randomly assigned (like the flip of a coin) to receive either canagliflozin (hereafter referred to as "study treatment") or placebo. This dose of canagliflozin used in this study is 300mg once daily, which is the same dose that is used in the treatment of type 2 diabetes. A placebo is an inactive pill that looks like the study drug, but a placebo contains no active medication. Placebos are used to help determine if the results of the study are truly from the study drug. You will not be able to choose the study group to which you will be assigned. Neither you nor the study investigators will know which agent you are receiving. However, this information can be learned in case of an emergency.

   The chance that you will receive study treatment or placebo is equal: half of the study participants will receive study treatment and half will receive placebo.

3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

   Enrollment visit (Study Week 0)
   You will come to this visit after an overnight fast. At this visit we will measure your vital signs, body composition, and resting metabolic rate. We will also give you study treatment or placebo. We will give you enough pills to last until your next study visit.

   Vital signs: For all visits, this will include weight, blood pressure lying down and standing, heart rate lying down and standing, and waist circumference
   Body composition: We will measure your body composition using a dual energy x-ray absorptiometry (DXA) scan. During this scan, you will lay flat and still on a table connected to the DXA machine. You will be asked to remove all metal on your entire body. The DXA scanner has an arm-like device that will take Xray images of your fat and lean muscle as it passes over you. The DXA scan will take approximately 15 minutes.
   Resting metabolic rate: Your resting metabolic rate (RMR) is the number of calories your body burns while you are at rest. You will be asked to lay in bed and breathe comfortably without falling asleep for about 20 minutes. We will then place a large plastic dome over your head, including your nose and mouth, and we will measure the air you breathe in and out. The plastic dome is not tight fitting. The plastic dome will be over your head for about 20 minutes.
   Blood sugar logs: We will provide you with blood sugar logs for recording your blood sugar levels at least once every day. If you already have your own blood sugar logs, you will be allowed to use those while you are in the study.

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Visual analog scales: We will assess your degree of hunger or fullness. You will be asked to draw a vertical line through a 10cm horizontal line, with one end representing hunger and the other end representing fullness. We will give you copies of this scale to complete twice per week, once in the fasting state and once 2 hours after a meal.
Food recall and food logs: You will be asked to name all of the food you ate in the 24 hours prior to the screening visit so that we can understand your baseline eating habits.
Study Treatment Dispensing: You will be given enough study medication to last until your next visit. You will take one tablet or capsule (canagliflozin 300mg tablet or placebo capsule) once daily throughout the study.

Follow-up visits (Study weeks 2, 4, 8, 12)

You will come to all follow-up visits after an overnight fast. Follow-up visits will include these procedures:

- Urine pregnancy test if you were required to have one at the screening visit.
- We will review adverse effects, changes in your medical history, blood sugar logs and compliance with study treatment/placebo
- We will measure your vital signs, as we did at the screening visit
- We will collect a urine sample for measurement of glucose and protein. We may also obtain a urinalysis or urine culture if deemed necessary.
- We will measure your resting metabolic rate
- We will collect food logs and visual analog scales
- We will give you an additional supply of study treatment or placebo, enough to last until your next visit.

- You will continue to take the study treatment or placebo. You will take one tablet or capsule (canagliflozin 300mg tablet or placebo capsule) once daily throughout the study.

Final study visit (Study week 18)
You will come to the final study visit after an overnight fast. Study procedures at this visit are the same as those done at the enrollment visit (except giving you study treatment or placebo), discussed in detail above. These include vital signs, body composition (using both DXA scan, resting metabolic rate, and blood and urine tests.

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RISKS 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.

Canagliflozin:. As of 28 September 2015 approximately 13173 subjects have received canagliflozin in completed or ongoing studies of 12 weeks or longer.

In this study, the dose of canagliflozin is the same as the dose used in clinical care for the treatment of type 2 diabetes. Side effects found in these studies that are more likely to occur with canagliflozin include those below.

More Common: These occur in up to 1 in 20 people

- Hypoglycemia: If you take canagliflozin with another medicine that can cause low blood sugar, such as a sulfonylurea, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine may need to be lowered while you take canagliflozin, and the study doctor will speak to your doctor about any changes in your usual diabetes medications. Hypoglycemia may occur in more than 1 in 10 people on canagliflozin. Symptoms of hypoglycemia include headache, drowsiness, confusion, weakness, feeling jittery, feeling irritable, feeling hungry, sweating, or having a fast heart beat. We will ask about these symptoms at every study visit.

- Dizziness or lightheadedness upon standing: These symptoms may occur from a decrease in blood pressure, can occur soon after starting canagliflozin, and are more likely to occur in people on medicines to lower blood pressure including diuretics (water pills such as furosemide), on a low salt diet, older patients or those who have reduced kidney function. While you are participating in this study, you should try to avoid becoming dehydrated and you should speak to the study doctor about any changes in your diet or other medications. This side effect may occur in up to 1 in 20 people on canagliflozin, or slightly more frequently in those at risk as described above.

- For Women: Vaginal yeast infections and vaginal itching: You may have symptoms such as vaginal itching, burning, irritation, odor or discharge. This side effect may occur in slightly more than 1 in 10 women on canagliflozin.

- For Men: Yeast infection at the head of the penis - You may have symptoms such as penile itching, irritation, burning, swelling, foul smelling discharge or pain. In 0.3% (3 in 1000) of men who are not circumcised, this could lead to swelling of the foreskin, and

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require circumcision. The side effect of yeast infection may occur in up to 1 in 20 men on canagliflozin

- Increased urination and thirst – Symptoms might include feeling thirsty, having a dry tongue, urinating more frequently or in larger amounts, an urgent need to urinate or more frequent urination at night. These side effects may occur in up to 1 in 20 people taking canagliflozin.

- Urinary tract infections – Symptoms of urinary tract infections may include burning with urination, discomfort in passing urine, or fever. This side effect may occur in up to 1 in 20 people on canagliflozin.

- Allergic reaction including rash or hives – These events can occur shortly after starting canagliflozin, are generally not serious or associated with other serious symptoms, such as breathing problems. This side effect may occur in up to 1 in 20 people on canagliflozin.

Less Common These occur in fewer than 1 in 20 people but in more than 1 in 100 people

- Constipation – The side effect of constipation may occur in slightly more than 1 in 50 people on canagliflozin.

- Nausea - The side effect of nausea (stomach queasy) may occur in slightly more than 1 in 50 people on canagliflozin.

- Bone fractures may occur in up to 1 in 50 people per year on canagliflozin.

- Amputation of the toes (and to a lesser extent the foot or leg) could occur in up to 1 in 150 people per year on canagliflozin. This risk is greater in those with a prior history of amputation, disease of the circulation involving the legs or in those with nerve damage due to diabetes.

- Laboratory changes that have been observed in clinical studies with canagliflozin
    - Your blood test might show an increase in the LDL, or "bad", cholesterol.
    - Your blood test might show an increase in serum potassium, phosphate and/or hemoglobin; decreases in serum urate can also occur. These changes are generally not serious and not associated with serious symptoms.

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o A change in lab tests associated with your kidney function might occur. These changes have generally been temporary and may relate to hydration status. Cases of severe decreases in kidney function have been reported more commonly in patients who were dehydrated. During the study, your doctor regularly monitors your kidney function, and may discuss with you any necessary changes in your diet or other medications.

- **Diabetic ketoacidosis** - Your blood may show increased levels of blood acids called ketones. Sometimes this can occur even if your blood sugar levels are not very high (e.g., less than 250 mg/dL [13.9 mmol/L]). The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness. Symptoms may include difficulty breathing, nausea, vomiting, excessive thirst, rapid weight loss, abdominal pain, confusion, fruity-smelling breath, a sweet or metallic taste in your mouth, a different odor to your urine or sweat, and unusual fatigue or sleepiness. This side effect may occur in up to 1 in 1000 people with Type 2 diabetes. Call your doctor if you experience these symptoms. Do not stop or change study drug or diabetes medicines without first discussing with your doctor.

- Serious allergic reactions, including those with the symptoms of swelling of the face, throat, and/or tongue or breathing problems.

- Related to changes in lab tests associated with kidney function, severe cases of decreases in kidney function have been reported more commonly in patients who were dehydrated.

- Infections of the urinary tract that can spread to the kidneys or into the bloodstream. Symptoms may include high fever, increased heart rate and breathing, low blood pressure, low urine output and lower back pain. Call your doctor if you experience these symptoms.

- Side effects in patients not involved in clinical studies who have been prescribed canagliflozin to treat their diabetes include those above. It is difficult to know specifically how often these side effects occur or always be certain if they are more likely to occur as a result of canagliflozin because these were not reported in the manner similar to data collection in a clinical study.

- There may be side effects with the use of canagliflozin that are not yet known. Sometimes during a study Janssen Pharmaceuticals may learn new facts about the study treatment. It is possible that this information might make you change your mind about

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being in the study. If new information is discovered, your study doctor will inform you of such new information in a timely manner.

Risks Associated with Blood Draw: 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.

Risks Associated with Indirect calorimetry: You may feel like you are suffocating or need air when we measure your resting energy expenditure. If this happens, we can stop the test.

Risks Associated with DXA scan: The DXA scan is a not an invasive procedure and there are no risk associated with the procedure itself. Because the DXA scan includes an Xray, you will be exposed to a small amount of radiation for each scan. This research study involves exposure to radiation from body composition scans. This radiation exposure is **not** necessary for your medical care and is for research purposes only. This is in addition to the radiation exposure that you will receive as part of standard care. Using the standard way of describing radiation exposure, from participating in this study you will receive a total of 0.04 mSv.

For comparison, the average person in the United States receives a radiation exposure of 3 mSv per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in about one week from these natural sources.

One possible effect that could occur at these doses is a slight increase in the risk of cancer. Please be aware that the natural chance of a person getting a fatal cancer during his/her lifetime is about 1 out of 4 (or 25 percent). The increase in the chance of getting a fatal cancer, as a result of the radiation exposure received from this research study, is less than 1 in 25,000 (or much less than 1/100th of a percent). Therefore, the total risk of fatal cancer may be estimated to increase from 25 percent to 25.01 percent. This additional risk is too small to be measured and is generally regarded as insignificant.

Another concern some people may have about radiation exposure is the effect on fertility or on the possibility of causing harm to future children (i.e., genetic effects). The doses you will receive in the study are well below the known levels needed to affect fertility or cause genetic effects.

If you are pregnant or breast feeding, you may not participate in this research study. It is best to

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avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults.

PREGNANCY

Because of the effects of this (these) study medication(s) on the developing fetus is (are) not known, you may not participate in this study if you are pregnant.

You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first (both) dose(s) of the study medication(s).

Furthermore, if you are a woman capable of becoming pregnant, you must agree to use adequate birth control. For the purpose of this study, use of adequate birth control includes one of the following:

1. oral hormonal contraceptives;
2. implanted hormonal contraceptives
3. diaphragm with spermicide;
4. condoms;
5. Intra-uterine device;
6. abstinence.

If you believe you have become pregnant while participating in this study, you must inform your study investigators immediately. They will have you take a pregnancy test. If the results demonstrate that you are pregnant, you must withdraw from the study, and the study investigators will ask to monitor your pregnancy and the health of your baby. To monitor your pregnancy may include (but not limited to) office visits, blood work, and questionnaires.

If you are a man capable of fathering children, you must use adequate contraception while participating in this study. For the purposes of this study, adequate birth control means;

1. use of a condom
2. your partner must use an approved method of birth control as listed above.

For male subjects, if your partner becomes pregnant, you must tell the study doctor immediately.

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.

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However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

In some situations, it is possible that you would be placed at risk for legal criminal prosecution or other legal problems.

There may also be damage to your future financial standing, health care, employment, professional standing or ability to get access to health or other insurance.

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 agencies, and by the drug manufacturer, Janssen Pharmaceuticals, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration 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.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation 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 have the following options: You may continue to receive your usual care for type 2 diabetes.

It is important to note that it is possible to get canagliflozin even if you do not take part in the study, since it is an FDA-approved treatment for type 2 diabetes. 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.

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.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

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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. 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.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

However, please be aware that there may be risks to leaving the study before it has been completed. In particular, your blood sugar levels may change, which could require you to see your doctor more often and/or test your blood sugar more often.

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 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 canagliflozin or placebo or any study measurements including vital signs, body composition, resting metabolic rate, or blood or urine tests that are part of this research study. 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.

PAYMENTS TO YOU:

You will be paid $25 for the screening visit and for each of the follow-up visits. You will be paid $50 for the enrollment and final study visits. You will also be given a parking sticker at each visit. You will receive a check after the study week 8 follow-up visit and after the final study visit. It may take up to 8 weeks for you to receive payment by check.

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

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or more in one calendar year for taking part in one or more research studies at BIDMC. 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 "Whom 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 to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure 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 (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

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

Your Protected Health Information may be shared with and used by investigators listed on this consent form as well as the supporting research team [i.e. research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, administrative assistants], and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

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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 funding source of this study, Janssen Scientific Affairs, LLC and, where applicable, the people and companies that the funding source use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

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 research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For

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example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. 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.

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 Dr. Jody Dushay at 330 Brookline Ave., Boston, MA 02215. 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, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, 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.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 667-0469 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with

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TITLE OF RESEARCH PROTOCOL: MECHANISMS OF WEIGHT LOSS WITH SGLT2 INHIBITION
PRINCIPAL INVESTIGATOR'S NAME: JODY DUSHAY MD
PROTOCOL #: 2014P-000335

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
10/10/2017
APPROVAL EXPIRATION DATE

questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

ICF REVISION DATES:
12/5/14: Full Board required modifications
3/25/15: Add Co Investigator Alexandra Migdal
7/15/15: Revised risk language
01/28/16: Revised risk language and urine sample collection if needed to protocol

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 pages 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) at [617]667-0469.

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

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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

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.

SUBJECT'S NAME:
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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: _____