Subject's Name	
Principal Investigator	**Mary Elizabeth Patti MD**
Study Title	**Mechanisms of Hypoglycemia in Patients without Diabetes**

Introduction

This is a long and important document. This document describes a research study and explains how your medical information will be used and/or disclosed for the purposes of this research study, if you choose to participate.

You should take the time to read this document carefully. If you choose, you may take a copy of this document to discuss with your physician, legal counsel, family member or anyone else you would like before signing it.

This document may contain information or words that are difficult to understand. It is very important that you ask the study investigator or a member of the study staff to explain any words or information that you do not understand.

Your participation in this research study is completely voluntary. If you agree to participate in this study, you will be asked to sign this form to show your consent to participate and your authorization for the use and/or disclosure of your medical information.

Do not sign this document unless you are comfortable with your decisions regarding both your consent to participate in this research study and your authorization for the use and/or disclosure of your medical information for this research study.

Study Purpose

The purpose of this study is to learn more about the causes of hypoglycemia (low blood sugar).

Study Participants

You are being asked to participate in this research study because you either have hypoglycemia, or you are healthy, and being studied in comparison to those with this condition.

This study will take place at Joslin Diabetes Center.

Study Sponsor / Funding

This study is being done at Joslin Diabetes Center by Dr. Mary Elizabeth Patti and her research team.

This study is being funded by the National Institutes of Health.

Study Details / Procedures

This study involves 1 or 2 visits to the Joslin Diabetes Center.

Visit 1 (Screening)
This visit will last about 2 hours.

At this visit, a detailed medical history will be taken and you will have a physical examination. You will have your weight, blood pressure, and pulse taken and recorded. You will be asked to complete questionnaires about your symptoms and health. You will also have an EKG (an electrical tracing of your heart). You will have a blood sample drawn (about 2 tablespoons) for basic laboratory studies, including kidney and liver function testing, and for genetic (DNA) testing.

We will ask you to sign a release of information form so that we may obtain additional information about your medical history from prior physicians and hospitals.
You will be provided a kit and instructions to collect a stool sample at home. We will ask you to collect the samples from a toilet hat and place a small sample into each of two collection tubes and ship it back to Joslin with a cold pack and mailing materials which will be provided to you.

Optional Visit 2 (Mixed Meal Tolerance Test)
Some participants will be invited to participate in a second visit, based on their medical history. This visit will last about 7.5 hours, and will occur within 14 days after visit 1.

The purpose of the Mixed Meal Tolerance Test (MMTT) is to determine how your body's hormones respond when you eat a meal likely to cause hypoglycemia. During your time in the clinic research unit, we will monitor you and your glucose levels closely, and perform laboratory tests in order to study how a variety of hormones, which control blood glucose levels, respond when you have eaten.

For this visit, you will return to the Joslin Diabetes Center after an overnight fast (no food or drink other than water after midnight) between 07:30 and 09:00 in the morning. However, if you have a low blood sugar reaction, you will need to treat the low blood sugar with food to ensure your safety. The visit may then need to be rescheduled.

A brief medical history will be taken. Your weight, blood pressure, and pulse will be taken and recorded. A part of your physical examination will be repeated.

For the MMTT, you will have two small plastic tubes placed into two veins of your arms; these intravenous lines, or IVs, will be used to obtain blood samples necessary for the test. At the start of the test, you will have blood drawn to look at your laboratory values of hormones, glucose and insulin, and blood count (hematocrit). The function and accuracy of the glucose sensor will be verified using at least 2 blood glucose samples obtained 15 minutes apart. You will then be given a nutritional drink (Ensure Compact) to consume over a 5-minute period and then have blood samples drawn at 10, 20, 30, 60, 90, 120, and 180 minutes after finishing the drink. During the test, your blood sugar, blood count (hematocrit) and vital signs will also be monitored immediately at each time point. Symptoms of hypoglycemia will be assessed at each time point (or any other time you have symptoms) using the Edinburgh scale.

At any time point, if blood glucose levels fall below 90 mg/dl, glucose will be measured at 5 minute intervals using a laboratory machine in the room (YSI).

If your glucose level falls below 50 mg/dl or if you develop significant signs and symptoms of hypoglycemia, we will provide you with glucose to rapidly restore your glucose to a normal level. If the intravenous line is functioning then you will receive glucose through the intravenous line. However if the intravenous line is not functioning and you have a low glucose with severe symptoms the study nurse or physician will inject you with standard FDA-approved glucagon 1 mg by injection under your skin. An intravenous line will be re-established to monitor response to therapy and to provide additional glucose if necessary. Your blood glucose will be reassessed every 5 minutes, and treatment repeated if glucose level remains under 50 mg/dl at 15 minutes after treatment. If your blood glucose remains below 70 mg/dL and you are able to swallow we will provide 1-4 dextrose tablets (4-16 grams of carbohydrate) as determined by the study physician. Once your blood sugar has been restored above 70 mg/dL and your signs and symptoms of hypoglycemia have resolved, then you will be provided a standard meal.

If you have not developed hypoglycemia, you will be provided lunch after the 180 minute blood samples are collected. Following the meal, your venous blood glucose will be monitored every 15 minutes for at least 2 hours to be sure that the glucose remains stable prior to discharge from the clinical research unit.

After the meal testing is completed, you will be connected to a continuous glucose monitor (CGM). The CGM will measure the sugar in your body over the course of up to 10 days; however, you will not be able to see the glucose readings from the CGM while you are wearing it. If you ordinarily check your blood glucose levels, you should continue to do so as you normally would using your glucometer.

The CGM consists of a sensor, transmitter, and receiver. The sensor measures the glucose in the fluid under the skin. The transmitter receives the information about the sugar level and the receiver collects and stores the sugar values. A member of the study team will insert a sensor under the skin of your stomach (abdominal wall) using a small needle and connect it to the transmitter. Instructions will be provided about how to carry the receiver and shower while the sensor is attached to your body.

The study team will provide the CGM (sensor, transmitter and receiver). The sensor is disposable (used only by you) and the transmitter and receiver will be returned in the mail to the study team. (The mailing materials will be provided to you.)

In addition you will receive a glucometer, a device that measures your blood sugar using a small amount of blood obtained by a finger stick. You will be instructed how to use the glucometer and will be asked to measure your blood sugar 4 times a day and keep a record of these measurements as well as the timing and content of your meals and your activity. You will be able to keep the glucometer after completion of the study.

You will also be provided a FitBit to wear at the same time as the CGM, over the course of the same 10 day period. The FitBit will record heart rate and total activity throughout the day.
You will be asked to complete a food and activity diary, so we can match these with glucose information.

Prior to discharge, the intravenous lines will be removed, and a band aid will be applied to each site. Blood samples will be frozen and stored for analysis of insulin, glucagon, and other hormones to assess how your body responded to the meal.

At any point during the study visit, if you develop severe nausea, abdominal pain or if you feel you need to stop, you will be able to just raise your hand and we will stop the procedure.

The total amount of blood taken for this test will be up to a maximum of 252 ml (17 tablespoons).

You will remove the FitBit, CGM sensor, and CGM transmitter, and return these devices to the study team for analysis. Mailing materials will be provided to you. Once the equipment is returned to the study team, the information will be downloaded.

Any equipment that touches your skin such as the continuous glucose monitor transmitter will be cleaned and disinfected by the study team according to the manufacturer's instructions after being used. The equipment will be stored in a clean zipper bag.

One of the study clinicians will follow up with you to collect information about symptoms, glucose values and any side effects, you may have experienced one day after the study visit.

The total duration of this study (1 or 2 visits) will occur up to a maximum of 3 weeks.

Samples collected

DNA (genetic) analysis

The study team will collect a blood sample to be used to isolate and analyze DNA to identify differences in genes which may be associated with risk for hypoglycemia. If I do not want to have my DNA collected and analyzed, I must check the box below and initial this statement.

☐ I authorize the study team to collect and analyze my DNA.
_____ Participant's Initials

☐ I **do not** authorize the study team to collect and analyze my DNA.
_____ Participant's Initials

Reports of study visits and laboratory testing

The study team will notify your primary care provider and primary endocrinologist, as needed, regarding your study participation, and will provide clinically significant results of your study visits and laboratory tests to you and your primary care provider. If you do not have a primary care provider, assistance will be provided to help you identify one.

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

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

You may also elect to have a letter containing clinically significant results sent to you at the conclusion of the study.

☐ 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

Study Risks / Discomforts

Participating in research studies often involves some risks, possible risks and/or discomforts.
Risks regarding participation include risks associated with:

(1) Drawing Blood/IV Insertion
At the time the blood is obtained, you may feel a sharp stinging sensation from the needle stick. Occasionally, a black and blue mark or small blood clot (phlebitis) may develop at the puncture site. These complications usually resolve spontaneously or with local heat application. On very rare occasions, a nerve under the skin may be damaged and cause numbness in part of the arm.

A slow infusion of isotonic saline (normal, or 0.9%) is used to keep intravenous lines open. This should not cause any side effects.

The maximum volume of blood taken during the entire study is a maximum of 282 ml (19 tablespoons) for both visits. If only visit 1 is completed, the total volume of blood is about 30 ml (2 tablespoons). (The amount of blood taken may be lower, depending on your glucose responses during testing.) This should not pose significant health risk to you. If your blood count is low on visit 1, you will not be able to participate. You should not have donated blood for 2 months prior to the study and you should not donate blood for 2 months after participation in the study.

(2) Continuous Glucose Monitor (CGM) and glucose testing
Potential adverse effects related to CGM include skin irritation (redness or rash), itching, bruising, discomfort, pain, and bleeding when the devices are inserted. There is also a low risk of infection at the insertion site. If you notice any redness or pain at the insertion site, the sensor should be removed.

After the sensors are removed, you may feel some skin irritation from the adhesive that was used to attach the pump and sensor. This irritation usually goes away within a few hours. During those hours, the skin may itch.

There have been a few reports of the CGM sensor tip breaking off and remaining under the skin. This is a very rare event, occurring in about 2 in 10,000 sensor uses. If this were to occur, it is recommended to do nothing as there is no report of harm; the sensor tip often comes out by itself like a splinter or remains under the skin harmlessly.

The Dexcom G4 or G6 professional glucose monitoring system is the same type which is used by doctors to help with learning about patterns of glucose levels in patients. The sensor (the component of the system that enters the skin) will be used only by you and then discarded. Other parts of the system are re-used by multiple study participants after disinfection. These include the transmitter, which is the part attached to the sensor but remains on the outside of the skin, and the receiver, which is the hand-held device. Both of these parts will be used only after extensive cleaning with a bleach disinfectant, following manufacturer's recommended protocols. This process has been shown to eliminate bacteria and viruses.

A new glucometer will be provided for your use during the study.

(3) Meal Tolerance Testing
You may have some mild nausea or upset stomach ("dumping syndrome") from the nutritional drink that you need to take for this test. The test meal may lower your blood sugar. Your blood sugar will be monitored during the study to help prevent this from happening. If your sugar level does drop too low, you will be given glucose or standard glucagon to raise it quickly. Sometimes the blood sugar gets high during the mixed meal testing; should your blood sugar level become high, your body will be able to bring it down on its own.

(6) Stool collection
Collecting stool may be somewhat unpleasant for you.

(7) Screening Tests and Procedures
It is possible that as a result of the screening process you may learn that you have a health disorder that you are unaware you have. Every effort will be made to help you obtain the care you need. Results will be shared with you, and with your consent, with your primary care providers.

(8) Breach of Confidentiality
While every effort will be made to protect confidentiality of your identifiable information, there is the potential loss of confidentiality by participating in this study. To minimize this risk, all samples are labeled only with a unique set of letters and numbers (code) unique to both you and the study. The link between you and the code is maintained solely at Joslin. Since the consent form, medical records, and other documents may contain identification, to further prevent re-identification, a second code would be assigned at the time of sample or data transfer for use by other scientists at Joslin and other locations. This code would also be maintained solely at Joslin.

(9) DNA Collection for Future Genotyping:
You may opt-out for DNA collection. If you consent, a part of the blood samples provided by you may be used to extract a chemical called DNA. DNA is the genetic material (including the genes which are the blueprint for yourself) that you inherited from your parents and passed on to any of your children. Your DNA may be examined for genes and gene products that are involved in hypoglycemia, response to bariatric surgery, obesity and/or diabetes, or areas where the genetic marks are different between groups. Your DNA may be examined by researchers at Joslin Diabetes Center or may be shared with researchers at other institutions. In all cases, only deidentified material may be shared, so it cannot be linked back to individual participants in the study.

(10) FitBit activity monitor
Wearing a Fit Bit activity monitor may rarely cause a rash on your skin under the monitor.

(11) Inconvenience and Unknown Risks
You may be inconvenienced by the time commitment involved in participation in the study. There may be other risks from this study not known at this time.
You can choose not to participate in the clinical research project and can withdraw consent at any time.

In addition to the risks, possible risks and/or discomforts listed above, there may be risks/discomforts involved in this study that are not known at this time.

New Information and Questions

If any new information about the study becomes known that could affect you or might change your decision to participate in this research study, you will be contacted by the study investigator.

If you have any questions at any time about this study, you may contact the study investigator Mary-Elizabeth Patti MD at 617 309 2635 or the study coordinator Alexa Puleio at 617 309 4663.

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.

Alternative Procedures/Treatments

Since this study does not provide treatment, the only alternative is not to participate in the study.

Information for Women of Childbearing Potential

If you are a woman who is breast-feeding, pregnant, or wanting to become pregnant during the next 3 months, you may not participate in this study, as we do not know the risks of hypoglycemia for the developing child.

If you have not been surgically sterilized, or have not undergone menopause at least one year ago, you must use something to prevent pregnancy, such as systemic hormones (birth control pills, implant), intrauterine device (IUD), or a barrier method (diaphragm with intravaginal spermicide, cervical cap, male or female condom).

If you suspect that you have become pregnant at any time or do not use one of the contraceptive methods recommended by the study investigator, you must notify the study investigator or study staff immediately. If you become pregnant, you will not be allowed to continue your participation in this research study. The study investigator and/or study staff will follow the progress of your pregnancy and birth of your child.

Removal from Study

Your participation in this research study may be discontinued before you complete the study if circumstances arise which make this necessary. Your participation may be discontinued for any of the following reasons:

- Failure to follow the study protocol;
- Change in your medical condition;
- Discontinuation of the study for any reason by the sponsor, investigator, Joslin Diabetes Center, or government agencies;
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by research participants in this study.
- If you become pregnant or are unwilling to use appropriate contraception;
- If you decide to withdraw your consent for study participation;
- Evidence of allergy to products used during the study;
- Intolerable adverse events

If you are discontinued from the study for any reason, this will have no effect on your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Adverse Events or Injuries

If an adverse event or study-related injury occurs as a direct result of taking part in this study, you should immediately contact the study investigator, Dr. Mary Elizabeth Patti, MD, at 617-309-2635 or 617 838 6421. On evenings, weekends, and holidays, you should call the on-call Joslin doctor at 617-309-2400.

In the event of an adverse event or study related injury, you or your insurance company may be responsible for some or all of your medical costs for any necessary medical treatment, which will be arranged by Dr. Patti and the Joslin Diabetes Center.

It is not the policy of the Joslin Diabetes Center to provide free medical treatment or financial compensation for such things as lost wages, disability, and/or discomfort as a result of an adverse event or study related injury.

Anticipated Benefits

It is not expected that you will benefit directly from participating in this study. You should not expect your condition to improve as a result of participating in this research.

While there is no guarantee that you will benefit by participating in this study, future research studies and subjects may benefit from this study. We hope that by learning more about hypoglycemia, we will be able to develop better treatment approaches in the future.

Remuneration/Reimbursement

You will receive a parking voucher or be compensated for other travel expenses (up to $50) for each study visit.

Optional Visit 2 participants: You will receive CGM and FitBit supplies for the 10 day monitoring period, and glucose meter, and glucose test strips to use during the study. You will be able to keep the glucose meter, but will need to return the CGM and FitBit after completion of the study. You will be provided with a stipend of $50 for completion of visit 2.

You will be provided lunch during study visit 2.

If this study should result in the development of any marketable product, it is not the policy of the Joslin Diabetes Center to share any profits with participants in the research study.

Future Use of Data/Samples

Possible future use of collected identifiable samples/data/information:

Identifiable samples and/or identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable samples and/or identifiable private information may be used for future research of "many diseases or conditions". If the research investigator distributes your samples and/or information to other researchers or institutions, your samples and/or information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your samples or information.

If you have questions about storing samples or would like to request that samples be removed from storage, please let us know. It is not always possible to remove samples from storage or to retrieve samples from which identifiers have been removed and/or that have already been sent to other investigators.

Use of Your Samples/Tissue and/or Data for Commercial Development

As part of this research program, samples/tissue collected from your along with information about you and your medical history may be provided to other researchers and/or outside collaborators without identifying you by name. They may use your samples 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 and information 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. Joslin Diabetes Center has no program to compensate you in the event product testing or commercial development takes place.

Responsibility for Costs

In the event of an adverse event or study related injury, you or your insurance company may be responsible for some or all of your medical costs for any necessary medical treatment, which will be arranged by Dr. Mary Elizabeth Patti, MD, and the Joslin Diabetes Center.

It is not the policy of the Joslin Diabetes Center to provide free medical treatment or financial compensation for such things as lost wages, disability, and/or discomfort as a result of an adverse event or study related injury.

Right to Withhold or Withdraw Consent, or Refuse Procedures

Your consent to participate in this research study is completely voluntary. You do not have to give your consent, but you will not be allowed to participate in this research study without providing such consent.

At any time you may withdraw this consent and/or refuse a procedure.

If you withdraw your consent or refuse a procedure, you will not be allowed to continue your participation in this research study. To formally withdraw your consent to participate in this research study, you must provide a written and dated notice of this withdrawal to the study's investigator Mary Elizabeth Patti MD at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

If you refuse a procedure, you may withdraw from the study completely or continue without completing that procedure.

Whether or not you provide your consent to participate in this research study, withdraw your consent, or refuse a procedure will have no effect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. You will not be penalized or lose any other benefits to which you are otherwise entitled.

Privacy & Confidentiality – HIPAA Authorization

A federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, you must provide written authorization for the use and/or disclosure of your medical information in connection with research involving your treatment or medical records.

This section gives more specific information about the privacy and confidentiality of your medical information. It explains what medical information will be collected during this research study and who may use, disclose or receive your medical information. It also describes how you can revoke this authorization after you sign this document and your right to inspect your medical information.

We will only collect medical information that is needed for this research study. Your medical information will only be used and/or disclosed as explained in this document or as permitted by law.

The results of this research study may be published in scientific journals and/or presented at medical meetings. If the results of this study are published and/or presented, your identity will be kept confidential.

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 website will include a summary of the results. You can search this website at any time.

In addition to this document, you will receive the Joslin Diabetes Center's Notice of Privacy Practices, which provides more information on how the Joslin Diabetes Center can use and/or disclose your medical information. If you have not received the Joslin Diabetes Center's Notice of Privacy Practices, please ask the study investigator or a member of the study staff.

Medical Information Involved in this Study

This study may involve the use and/or disclosure of medical information already in your medical record here at Joslin and/or in another health care provider's records. The information that will be used will be limited to information concerning:

- Basic demographic information (e.g. date of birth)
- Medical history
- Medications
- Vital signs (e.g. blood pressure, height, weight)
- Laboratory test results (e.g. glucose, HbA1c, continuous glucose monitoring results)

This medical information will be used and/or disclosed only for the purpose of this research study.

Additionally, this research study may generate new medical information that will be placed in your research record and kept at Joslin Diabetes Center. The nature of the medical information resulting from your participation in this research study that will be placed in your research record includes:

- CGM data
- Blood glucose meter data
- Self-reported diet and activity
- Laboratory testing results
- Survey and interview responses
- Results from blood testing

This medical information will be used and/or disclosed only for the purpose of this research study.

Access to Medical Information Involved in this Study

In addition to the study investigators listed on the first page of this document and their study staff, the following individuals may have access to your medical information involved in this study:

- Authorized representatives of the Joslin Diabetes Center Audit and Compliance Office;
- Authorized representatives of the Joslin Diabetes Center Committee on Human Studies;
- Other medical centers/institutions/study investigators outside the Joslin Diabetes Center participating in this research study;
- The sponsor of this study, or its agents, such as data repositories or contract research organizations;
- Governmental entities that have the right to see and/or review research and/or your medical information, such as the Office of Human Research Protections and the Food and Drug Administration;
- Hospital and other accrediting agencies;
- Clinical staff not involved in this study who may become involved in your care, if the medical information is potentially relevant to treatment;
- Your health care insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for by this study;

All reasonable efforts will be used to protect the privacy and confidentiality of your medical information. However there is a risk of a breach of confidentiality that cannot be totally eliminated. To minimize this risk, study records will be kept in restricted areas at the Joslin Diabetes Center and computer access will be restricted by a password known only to the authorized members of the staff at the Joslin Diabetes Center. Information that could identify you, such as your name, will be maintained in a file separated from all study information. In spite of these efforts to protect the privacy and confidentiality of information about you, there is a risk that sensitive information may be obtained by others or discovered or inferred by members of your family. For example, a court of law may order Joslin to release confidential information about you.

Additionally, all reasonable efforts will be used to protect the privacy and confidentiality of your medical information when the Joslin Diabetes Center is authorized to disclose such information to others. However, if your medical information is disclosed to a party not required by law to keep it confidential, then that information may no longer be protected, and may subsequently be used and/or disclosed without your permission.

Right to Withhold or Withdraw Authorization

Your authorization to use and/or disclose your medical information for the purpose of this research study is completely voluntary. You do not have to give your authorization, but you will not be allowed to participate in this research study without providing such authorization. At any time you may withdraw this authorization, but you will not be allowed to continue your participation in this research study.

If you withdraw your authorization, no new medical information about you will be obtained. However, medical information obtained for, or resulting from, your participation in this research study prior to the date you formally withdrew your authorization may continue to be used and/or disclosed for the purpose of this research study.

To formally withdraw your authorization to use and/or disclose your medical information for the purpose of this research study, you must provide a written and dated notice of this withdrawal to the study's Principal Investigator, Dr. Mary Elizabeth Patti, at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

Whether or not you provide or withdraw your authorization for the use and/or disclosure of your medical information for the purpose of this research study will have no effect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with the Joslin Diabetes Center. Additionally, whether or not you provide or withdraw your authorization will have no effect on your current or future relationship with a healthcare insurance provider.

Continuation of Authorization

Your authorization to use and/or disclose your medical information will continue until you withdraw your authorization. Your medical information may continue to be used and/or disclosed for this research study for an indefinite period of time. This is because information and data that is collected for this study will continue to be analyzed for many years and it is not possible to determine when such analysis will be complete.

Access to Medical Information

Except for certain legal limitations, you are permitted access to any medical information obtained for, or resulting from, your participation in this research study. However, you may access this information only after the study is completed.

VOLUNTARY CONSENT & AUTHORIZATION

I understand that no one has contacted my primary care physician or any other doctor from whom I may be receiving care regarding my involvement in this research study. I understand that I should consult with any such doctor, and have been encouraged to do such, prior to participating in this study to discuss whether there is any reason he/she is aware of why I should not participate in this study.

I have been informed of and understand the purpose of the research study entitled "Mechanisms of Post-Bariatric Hypoglycemia" and the study's procedures. I have been informed of and understand the foreseeable risks, potential risks, discomforts, and benefits associated with this study. I have been advised of and understand that unforeseen complications may occur. I understand that I may or may not be entitled to free medical care or compensation in the event that I am injured as a result of my participation in this study. I understand that if this research study should result in the development of any marketable product, it is not expected that any profits would be shared with me.

I have been informed of and understand that my medical information may be used and/or disclosed for the purpose of this research study. I understand that the study investigators, study staff, and the Joslin Diabetes Center will make all reasonable efforts to protect my privacy and confidentiality. I have been advised of and understand that there is a risk that my medical information may be obtained by others. I have been advised of and understand that if others obtain my medical information, my medical information may no longer be protected, and may be subsequently used and/or disclosed without my permission. I have been informed of and understand that this study may be published or otherwise shared for scientific purposes. I understand that my name will not be published and that every reasonable effort will be made to protect my confidentiality.

I have been informed of and understand that my participation in this study is completely voluntary. I may refuse to consent to my participation in this study. Once enrolled in this study, I may withdraw my consent or refuse a procedure at any time. I may refuse to authorize the use and/or disclosure of my medical information for the purpose of this study. Once enrolled in this study, I may withdraw my authorization at any time. I have been informed of and understand that I will not be allowed to participate in this study, or continue my participation in this study, without both my consent and authorization.

I have read this document and been provided with the opportunity to discuss any questions and/or concerns regarding the research study and/or this document with the study investigator or a member of the study staff. I have received the Joslin Diabetes Center's Notice of Privacy Practices.

I have been informed of and understand that I may contact the Joslin Diabetes Center's Committee on Human Studies if I have questions regarding my rights as a research participant in this study. I may contact either:

- **Leigh A. Read, CIP**, Research Compliance & Programs Director at **(617) 309-2543**
- **Robert C. Stanton, M.D.**, CHS Chairperson, at **(617) 309-2477**

I have been informed of and understand that I may contact the Joslin Diabetes Center's Chief Audit and Compliance Office if I have questions regarding my rights associated with the use and/or disclosure of my medical information. I may contact:

- Joslin Diabetes Center's Compliance Officer, at **(617) 309-2400**

This is a legal document that may affect my legal rights, my rights to privacy and my medical conditions and information. I understand that I have had the opportunity to consult with legal counsel, and my own physician about this study before signing this form.

I, _____ hereby consent to participate in this study and authorize the use and/or disclosure of my medical information for this research study, as described in this document.

_____ _____

Signature of Participant or Participant's Representative *Date*

_____ _____

Participant or Participant's Representative (Print Name) *Relationship to Participant*

PLEASE NOTE

I do not have to provide my authorization for the use and/or disclosure of my medical information for this research study, as described in this document. If I do not want to provide my authorization, I must check the box below and initial this statement. If I do not provide my authorization, I may not be able to participate in this study.

☐ I **do not** authorize the use and/or disclosure of my medical information for this research study, as described in this document. _____ Participant's Initials

We would like to send results of clinical laboratory testing to your primary care physician as needed for your medical care. If I do not want to provide my authorization, I must check the box below and initial this statement.

☐ I **do not** authorize the use and/or disclosure of my medical information to my primary care physician for this research study, as described in this document. _____ Participant's Initials

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled "Mechanisms of Post-Bariatric Hypoglycemia", the nature of the study procedures, and such foreseeable risks, potential risks, discomforts, and benefits that may result from their participation in this study. This explanation was made in appropriate language. I have advised the above-named participant to contact their primary care doctor regarding his/her participation in this study, if such contact has not been previously made. I have asked the above-named participant if they have any questions and/or concerns regarding this research study or any of the study's procedures, and I have answered his/her questions to the best of my ability.

I hereby certify that I have explained to the above-named participant the nature and purpose of the use and/or disclosure of his/her medical information, including the possibility that his/her medical information may be obtained by others. This explanation was made in appropriate language. I have asked the above-named participant if they have any questions and/or concerns regarding the use and/or disclosure of his/her medical information for the purpose of this research study, and I have answered his/her questions to the best of my ability.

I hereby certify that I have informed the above-named participant that his/her participation in this research study is completely voluntary. To the best of my knowledge, the decisions made by the above-named participant regarding his/her consent and authorization are accurate reflections of his/her personal choices. To the best of my knowledge, the above-named participant has not been coerced or induced into his/her participation in this research study.

_____ _____

Signature of Investigator or Investigator's Representative *Date*

_____

Investigator or Investigator's Representative (Print Name)