Joslin Diabetes Center

Committee on Human Studies

Informed Consent & Authorization Form

Participant's Name: _____

Participant's Status: ☐ **Joslin Patient** ☐ **Non-Joslin Patient** ☐ **Employee**

Principal Investigator: Mary Elizabeth Patti, MD

Co-Investigator(s): Kathleen Foster, RN; Amanda Sheehan, NP; Alexa Puleio BS

Study Title: Determining the Efficacy of Continuous Glucose Monitoring to Reduce Hypoglycemia and Improve Safety in Patients with Hypoglycemia after Gastric Surgery

Study Sponsor: Dexcom

Study Contact: Mary Elizabeth Patti, MD x1966

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 any one 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.

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Purpose of Study

You are being asked to participate in a research study. The purpose of this study is to find out if use of a continuous glucose monitor by people who are experiencing low blood sugars (hypoglycemia) after gastric surgery can help reduce how often and how severe episodes of low blood sugar occur. This device is already approved by the FDA for monitoring of blood sugars in people with diabetes. This study will be looking to see if it has a similar benefit for people experiencing episodes of hypoglycemia.

You have been asked to participate in this study because you currently experience episodes of hypoglycemia. The purpose of this study is to see if wearing a continuous glucose monitor can help reduce either how often your low blood sugars occur or how severe they are.

If you do not have a compatible smart phone, you will not be able to receive the glucose information and will not be able to participate in this study.

This study will involve about 40 subjects, all of whom will be recruited from the Joslin Diabetes Center.

This study is being sponsored by (paid for) by Dexcom, the maker of the continuous glucose monitor.

Study Procedures

The proposed study is designed to assess the efficacy of personal CGM to reduce the frequency of hypoglycemia after gastric surgery. Specifically, you will wear a CGM for a total of 20 days. For the first 10 days , the monitor will record glucose levels, but you will not be aware of the values. During the second 10 days, you will be able to see the results of glucose levels immediately and be able to respond to the glucose levels. By comparing the first and second 10 day period, we will determine whether the glucose information can help persons with hypoglycemia to reduce the number and severity of hypoglycemia episodes.

Visit 1:
Screening: We will recruit adult men or women with history of severe hypoglycemia (low blood sugar) after gastric surgery. The study consent form will be reviewed in detail, and if you agree to participate you will be asked to sign the IRB-approved consent form. You will speak with a doctor about your medical history and have a brief physical exam and be asked some questions about your hypoglycemia. Blood and urine will be collected for screening laboratory testing including hemoglobin A1c, CBC, comprehensive chemistry, urinalysis, and pregnancy test (for women). You will also be asked to complete a survey about how hypoglycemia has affected your daily habits and activities.

CGM sensor placement and instruction: A CGM sensor and transmitter will be placed on your belly. The CGM will be set to masked mode so you will not see your blood sugar on the device. You will be provided a meter to test blood sugars and instructed in how to place the CGM sensor, how to check your blood sugar with the meter, and how to use the CGM. You will be given a log for you to keep track of symptoms, blood sugars and treatment of symptoms. You will be given a spare sensor in case the one put on by study staff is dislodged. You will also be given a fitness tracker (FitBit Charge 2) to be worn throughout the duration of the 20 days of monitoring, and will be instructed in its use. This tracker will provide information about your activity level, and the relationship to any hypoglycemia you may have.

Visit 2:
Insertion of the second sensor: This visit will occur 10ays after visit 1. Study staff will remove the sensor, and review your diaries. A new sensor will be inserted.. The study CGM will be unmasked (which means you will now be able to see your blood sugar on the display), and alarms will be set for low blood sugar and quickly falling blood sugar. The study team will go over the meaning of alarms and suggested responses to alarms. You will be provided logs identical to those from visit 1, except that you will also be

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asked to record alarms and how you responded to the alarms. You will also be asked to answer some questions about your hypoglycemia at this visit.

Visit 3:

Return of study materials and removal of 2nd sensor: This visit will occur 10 days after visit 2. Study staff will remove the sensor, and review your diaries. Activity trackers will be returned to study staff. You will also be asked to answer some questions about your hypoglycemia at this visit. The study doctor will review how often you had episodes of hypoglycemia and any suggestions for changes to your diet or medications.

Risks, Potential Risks and/or Discomforts

Participating in research studies often involves some risks, possible risks and/or discomforts.

Continuous Glucose Monitor (CGM)

Potential adverse effects related to the 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 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 and the sensor tip often comes out by itself like a splinter or remains under the skin harmlessly.

Taking medications with acetaminophen while wearing the Dexcom CGM may inaccurately raise the sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and is different for each person. Do not rely on CGM data if you have recently taken more than 1000 mg of acetaminophen in a 6 hour period (or more than 4000 mg in 24 hours).

Drawing Blood

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. This study only requires a small volume of blood (approximately 15ml or 1 tablespoon).

Unknown Risks

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 **Dexcom G6 system** 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 617-309-1966** or the study coordinator at 617-309-4663.

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Alternative Procedures/Treatments

You do not have to participate in this study to receive treatment for your condition. There are other treatments currently available. They include treatments you are currently taking that are not being tested in this study, as well as changes to your diet **and continuing to check your blood sugars multiple times daily using a glucometer.** The study doctor can discuss these treatments with you.

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; or
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by research participants in this study.
- If your hypoglycemic episodes worsen in frequency or severity or
- If you have intolerable side effects from, or an allergic reaction to glucagon

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 **Mary Elizabeth Patti, MD at 617-309-1966** (day) or the study coordinator Lauren Richardson at 617-309-4463. If you need to reach study staff after 5 PM, please call 617-632-2337, beeper 81959.

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 **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.

Anticipated Benefits

Based on experience with this **continuous glucose monitor**, researchers believe it may be of benefit to subjects with your condition. Of course, because individuals respond differently to treatment, no one can know in advance if it will be helpful in your particular case. The potential benefits may include improved ability to identify and potentially prevent your blood sugars from dropping low.

While there is no guarantee that you will benefit by participating in this study, future research studies and subjects may benefit from this study.

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Remuneration/Reimbursement

You will be given a payment of $200.00 (provided as check) upon the completion of five study visits. The study will also compensate you for the cost of parking or taxi services up to $50 for each of the study visits.

Parking will be paid by vouchers on the days you are asked to come in for a study visit.

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.

Responsibility for Costs

All study related tests, procedures, and/or medications will be provided to you at no cost. Your or your insurance company will not be billed for the costs of study related procedures, tests, and/or medications.

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.

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.

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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.

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:

- Your general medical history
- Your history of gastric bypass surgery
- Your history of low blood sugar levels after bypass surgery, and any treatments that have been
- attempted for this condition
- Any procedures you have had to investigate the cause of the low blood sugars, or to attempt to improve it
- Laboratory studies that have been done to better understand the low blood sugar episodes, or in relation to your general medical health

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:

- Your blood sugar and low blood sugar events logs, and the effect of continuous sensor and infusion pump on these parameters
- Your clinical response to sensor-guided delivery of glucagon from an infusion pump

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;
- The sponsor of this study, or its agents, such as Dexcom
- 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

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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, Mary Elizabeth Patti, MD 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 efect 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.

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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 "Determining the Efficacy of Continuous Glucose Monitoring to Reduce Hypoglycemia and Improve Safety in Patients with Hypoglycemia after Gastric Surgery" 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**, CHS Program Administrator, 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**

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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

Participant's Initials: _____

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled "Determining the Efficacy of Continuous Glucose Monitoring to Reduce Hypoglycemia and Improve Safety in Patients with Hypoglycemia after Gastric Surgery", 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)

Participant's Initials: _____