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: Elena Toschi, MD

Co-Investigator(s): Emmy Suhl MS, RD, LDN, CDE; Stephanie Edwards, MPH; Astrid Atakov Castillo, BA; Katie Joyal, BS; Owen Henn

Study Title: Use of Mobile-Based Technologies to Improve Diabetes Self-Management and Postprandial Glucose Control

Study Funded by: Abbott Diabetes Care

Study Contact: Stephanie Edwards, MPH 617-309-1996

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.

APPROVED BY THE
JOSLIN DIABETES CENTER
COMMITTEE ON HUMAN STUDIES
Do Not Use After
MARCH 16, 2018

Participant's Initials: _____

Purpose of Study

You are being asked to participate in a research study. The primary purpose of this study is to assess a web-based nutrition education program that will provide you with guidance about the nutritional factors contributing to fluctuations in your glucose levels. The secondary purpose of this study is to assess a new smart phone application (app) called 'Sugar Sleuth'. This app will prompt you to enter information about your diabetes self-management with the goal of helping you to identify factors that cause glucose fluctuations. As part of this study you will be started on a glucose sensing device that will provide you with a more complete picture of your glucose levels than intermittent fingerstick blood glucose checks. The glucose sensor (an Abbott Libre sensor) is made up of the following parts: sensor, applicator, and a study smart phone with the Sugar Sleuth app used to read the glucose sensor. The Abbott Libre sensor has not been approved by the FDA and its use is limited to investigational use only.

You have been asked to participate in this study because you have type 1 diabetes.

This study will involve about 30 subjects at the Joslin Diabetes Center.

This study is being funded by Abbott Diabetes Care.

Study Procedures

Your participation in this study can last about 14 weeks. If you qualify for this study and decide to enroll, you will have five study visits to the Joslin Diabetes Center.

Visit 1 (Enrollment visit)
If you wish to participate in this study, you will be asked to read and sign this consent document before any study-specific procedures are performed. This visit could last up to 2 hours. The following procedures will be performed during visit one to determine whether you qualify to participate in this study:

- A review of the study requirements (inclusion and exclusion rules) will be performed.
- You will be asked about your medical history and the medications that you are currently taking.
- You will be asked information about your current diabetes treatment.
- Your height, weight, and blood pressure will be collected.
- The information from your home glucose monitor (HGM) will be obtained (downloaded).
- If you use an insulin pump, information from this device will be downloaded.
- You will be trained on the use of the Abbott Libre sensor and smart phone app Instructions will be provided to you in a separate document.
- You will be provided with a smart phone. This smart phone will only be for study purposes (use of the Sugar Sleuth app and viewing the nutrition education program). In order to protect your privacy, you may not use the study phone for personal matters (i.e., no web surfing, no personal phone calls, installing apps, etc.). **Per the instructions that will be provided to you, please remember that all diabetes management decisions must be made based on fingerstick glucose readings and not on continuous glucose readings from the study device.**
- You will be asked to maintain the use of the Abbott Libre sensor system in confidence. This includes not showing or sharing the system or any of the study materials with anyone who is not in the study or with anyone who is not a health care practitioner providing you with medical services, advice or care. The computer code (language) used to write the phone app has not yet

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been secured (encrypted), the app and all the information contained within is property of Abbott Diabetes Care and should not be obtained or shared as it is also an investigational use device.

- A blood sample will be collected for an A1c (approximately 1 tablespoon).
- You will have the option of completing the next visit in a group and can discuss this with the study investigators.

The next visit will be scheduled 14 days after visit 1.

Phone call
A member of the study team will call you to check up and to remind you of your next study visit. This call may last up to 15 minutes.

Visit 2
This visit could last up to 1 hour.
During this visit the following procedures will take place:

- Your HGM and insulin pump (if you use one) will be downloaded by a study staff member.
- Your sensor readings will be accessed by the study staff via a secure website.
- The study investigator will review the downloaded information and provide you with guidance on how to adjust insulin.
- The following training could be completed in a group, if you choose:
- You will be re-trained in the use of the Sugar Sleuth app, which will provide you with information about your previous glucose levels (measured every 15 minutes) as well as indicator arrows that will show whether your glucose is steady, increasing, or decreasing. Although you will have this added information from the Libre sensor about your glucose fluctuations, you will still need to do fingerstick blood glucose measurements (using your meter) whenever you take insulin for meals and also to decide how much insulin you need to treat high blood glucoses.
- The Sugar Sleuth app will be activated on your study smart phone.
    - If there are not 10 or more full days of glucose data on the app due to sensor failure or forgetting to scan the sensor with the smart phone at least every 8 hours, you may have to repeat the initial sensor wear.
- A member of the study staff will instruct you on:
    - How to access a web-based nutrition program and will bookmark it in the study phone.
    - How to enter events (amount of carbohydrate in meal and physical activity) information on the Sugar Sleuth app.
    - How to indicate:
        - Possible reasons for high and low glucose levels
        - Symptoms you experienced and any treatment action you took for low glucose levels
            - You will only be asked indicate this information after you've experienced high and low glucose levels.
        - You're not required to enter additional events (Notes) unless you wish to do so.
    - This information will be accessed during your next study visit.

The next visit will be scheduled 14-17 days after visit 2.

Phone call
A member of the study team will call you to check up and to remind you of your next study visit. This call may last up to 15 minutes.

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Visit 3
This visit can last up 1 ½ hour.
During this visit the following procedures will take place:

- You will be asked whether you have had difficulties with the Libre sensor or the app
- Your HGM, insulin pump (if you use one) will be downloaded by a study staff member
- Your sensor readings will be accessed by the study staff via a secure website
- Your downloaded information will be reviewed by one of the principal investigators
- You will be asked to meet with a registered dietitian or a member of the study team to review the food information you entered in the Sugar Sleuth app
- You will be asked to continue to indicate possible reasons for high and low glucose levels in the Sugar Sleuth app.

Visit 4 will be scheduled 4 weeks after this visit.

Phone calls
A member of the study team will call you weekly to check up and to remind you of your next study visit. These calls may last up to 15 minutes.

Visit 4
This visit can last up to 30 minutes.

- In between visit 3 and visit 4 one of the study PIs will review the glucose measurements from the Libre sensor as well as the information you entered into the Sugar Sleuth app. This information will be sent via the study smart phone to the PI.
- This will be a virtual visit. One of the study investigators will contact you via phone to discuss your glucose measurements and information entered by you into the app and he/she will make treatment recommendations. This visit can be completed in person at the Joslin Diabetes Center if you would prefer.

Visit 5 will be scheduled 6 weeks after visit 4.

Phone calls
A member of the study team will call you weekly to check up and to remind you of your next study visit. These calls may last up to 15 minutes.

Visit 5
This visit can last up to 2 hours.
During this visit the following procedures will take place:

- Your HGM, insulin pump (if you use one) will be downloaded by a study staff member.
- Your sensor readings will be accessed by the study staff via a secure website.
- You will be asked to complete 10 surveys about your diabetes and your experiences with using the glucose sensor. You will be asked for your feedback about the diabetes management recommendations you received during visit 4, and the diabetes management choices you made based on the information you learned during this study. You will also be asked how you feel about your experience logging information into the app.
- A blood sample will be collected for an A1c.
- All study devices (Libre sensors, applicators, and smart phone) will be returned during this visit.

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Risks, Potential Risks and/or Discomforts

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

Glucose Sensor
The glucose sensor may produce pain when it is inserted into the skin, similar to a pump site insertion or insulin injection. Rarely, a skin infection can occur at the site of insertion of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may occur. An allergy to the tape that holds the sensor to the skin is possible. The risk of skin problems could be greater if you use a sensor for longer than it is supposed to be used. There is a chance that the sensor or needle may break under your skin. This is not expected to occur; but, if it does, you should consult with your study doctor about what to do.

Questionnaires
You will be asked questions about your attitudes, feelings, and behavior related to diabetes. Though uncommon, it is possible that some people may find these questions to be mildly upsetting. There are no physical risks present. Many precautions will be made to keep your information confidential, but this is not a guarantee.

Group training
The group training may be upsetting because it may touch upon on your personal experience with your diabetes, including problems associated with diabetes and your experience with continuous glucose monitoring technology. The study investigators will make every attempt to minimize any discomfort that may arise. If at any time you feel uncomfortable or upset during the training, you can ask that the training be stopped. The entire training will stop, and you will be able to leave the group if you need to. You do not need to complete training in a group; individual training is also an option.

Blood Draw Risks
Possible risks from blood draws include the following: bruising, arm discomfort, clotting, excess bleeding, infection, or fainting. Please note that although these are possible risks they are unlikely.

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 you have any questions at any time about this study, you may contact the study investigator, Elena Toschi, MD, at 617-309-2645 or the study coordinator, Stephanie Edwards, at 617-309-1996.

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 your current diabetes treatment.

Information for Women of Childbearing Potential

If you are a woman who is breast-feeding, pregnant, or wanting to become pregnant during the next 13 weeks, you may not participate in this study.

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),

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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. If you become pregnant, you will not be allowed to continue your participation in this research study.

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 funder, 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 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 Elena Toschit, MD at 617-309-2645 or the study coordinator Stephanie Edwards, MPH, at 617-309-1996.

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 Elena Toschi, 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

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. This study is not being conducted to improve your condition or health.

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

Remuneration/Reimbursement

You will be reimbursed for parking during your study visits.

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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 and procedures will be provided to you at no cost. You or your insurance company will not be billed for the costs of study-related procedures and tests.

You or your insurance company may be responsible for the costs of some of the tests, procedures, and/or medications for this study. These may include your insulin, pump supplies and home glucose meter and strips.

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, Elena Toschi, MD at the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215.

If you refuse a procedure, you will be withdrawn from the study.

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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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:

- Diabetes history and treatment
- Glucose sensor, pump and food data from the app

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:

- Glucose sensor and food data from the app
- A1c
- Use of the nutrition education program

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 funder 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;

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 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.

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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. Elena Toschi, 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. Should you decide to leave the study, you must return all system components used in this study, including the study phone (reader), sensors and applicators, and continue to maintain them in confidence. 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.

Participant's Initials: _____

Joslin Diabetes Center, Informed Consent & Authorization (January 2007)

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 "Use of mobile-based technologies to improve diabetes self-management and postprandial glucose control" 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**

Participant's Initials: _____

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: _____

Joslin Diabetes Center, Informed Consent & Authorization (January 2007)

VERIFICATION OF EXPLANATION

I hereby certify that I have explained to the above-named participant the purpose of the study entitled "Use of mobile-based technologies to improve diabetes self-management and postprandial glucose control", 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: _____